

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

**DEPUY MITEK'S BRIEF IN RESPONSE TO ARTHREX'S CLAIM CONSTRUCTION
BRIEF RE: MITEK'S HUNTER PATENT -- U.S. PATENT NO. 5,314,446**

Table of Contents

I.	INTRODUCTION	1
II.	MITEK’S CONSTRUCTION OF “CONSISTING ESSENTIALLY OF” SHOULD BE ADOPTED.....	1
A.	The Specification Does Not Support Mitek’s Construction	1
B.	Arthrex Ignored the Prosecution History	2
III.	MITEK’S CONSTRUCTION OF “PE” SHOULD BE ADOPTED	2
A.	Reference to Proper Technical Dictionaries and Expert Testimony is Appropriate in Construing Terms of Art, Such as “PE”	3
B.	Arthrex Invites Legal Error by Trying to Incorporate Extraneous Limitations from the Specification into the Definition of “PE”	4
1.	Descriptions of Preferred Embodiments May Not Be Incorporated Into the Claims	5
2.	Arthrex Mischaracterizes the Patent Disclosure	6
3.	In Any Event, Ultra High Molecular Weight PE <i>Is</i> a Lubricious Material (and PET <i>Is</i> a Strong Material).....	8
C.	The Prosecution History Does Not Support Arthrex’s Position	10
IV.	CONCLUSION.....	12

Table of Authorities

Federal Cases

<i>C.R. Bard, Inc. v. U.S. Surgical Corp.</i> , 388 F.3d 858 (Fed. Cir. 2004).....	5
<i>Conoco, Inc. v. Energy & Environmental International, L.C.</i> , No. 05-1363,-1461, 2006 U.S. App. LEXIS 21036 (Fed. Cir. Aug. 17, 2006).....	3, 6
<i>Gemstar-TV Guide International, Inc. v. ITC</i> , 383 F.3d 1352 (Fed. Cir. 2004).....	1
<i>Innova/Pure Water, Inc. v. Safari Water Filtration System, Inc.</i> , 381 F.3d 1111 (Fed. Cir. 2004).....	3
<i>Intervet America, Inc. v. Kee-Vet Laboratories, Inc.</i> , 887 F.2d 1050 (Fed. Cir. 1989).....	5
<i>Lizardtech, Inc. v. Earth Resource Mapping, Inc.</i> , 424 F.3d 1336 (Fed. Cir. 2005).....	5
<i>NTP, Inc. v. Research in Motion</i> , 418 F.3d 1282 (Fed. Cir. 2005).....	3, 10
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005).....	3, 5
<i>Playtex Products, Inc. v. Procter & Gamble Co.</i> , 400 F.3d 901 (Fed. Cir. 2005).....	5
<i>Purdue Pharms. L.P. v. Endo Pharm. Inc.</i> , 438 F.3d 1123 (Fed. Cir. 2006).....	12

I. INTRODUCTION

Arthrex's claim construction positions are textbook examples of what the Federal Circuit has said a Court may not do when construing claims – ignore the plain meaning of the claim terms (to persons of skill in the art) and import limitations from the specification into the claims absent clear disclaimers or disavowals. For numerous reasons set forth below and in Mitek's Opening Claim Construction Brief, Arthrex's proposed constructions should be rejected.

II. MITEK'S CONSTRUCTION OF "CONSISTING ESSENTIALLY OF" SHOULD BE ADOPTED

Arthrex's argument in support of its construction of "consisting essentially of" is brief (Arthrex Op. Br. at 16-18), as will be Mitek's response.

A. The Specification Does Not Support Mitek's Construction

Arthrex improperly relies on discussion of *preferred embodiments* in the 446 Patent, rather than discussion of the invention as a whole, in support of its proposed definition of the "novel and basic characteristics" of the invention. Arthrex suggests that the novel and basic characteristics are improved handleability without sacrificing physical properties, but this discussion in the 446 Patent is provided only in connection with a discussion of preferred embodiments. *See, e.g.,* Ex. 1¹ at 2:62-66, 4:33-36. The Federal Circuit has proscribed using the disclosure of preferred embodiments to limit the scope of patent claims absent a clear disavowal by the inventor. *See, Gemstar-TV Guide Int'l, Inc. v. ITC*, 383 F.3d 1352, 1366 (Fed. Cir. 2004).

Mitek showed in its Opening Brief that its construction of the novel and basic characteristics of the invention – a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, here at least one yarn from the first set is in direct intertwining contact with a

¹ Citation to Exs. 1-13 refer to exhibits cited by Mitek in its opening Brief in Support of Its Claim Construction of the Hunter Patent – U.S. Patent No. 5,314,446, filed on August 11, 2006. Citation to Exs. 14-18 are being filed herewith.

yarn from the second set, and the dissimilar yarns having at least some different properties that contribute to the overall properties of the braid – is well-grounded in the specification and claims of the 446 Patent. Rather than repeat what has already been stated, Mitek refers the Court to pages 8-10 of its Opening Brief.

B. Arthrex Ignored the Prosecution History

As the cases cited in Mitek’s Opening Brief indicate, it is proper to look at why “consisting essentially of” language was added to a patent claim when determining the meaning of that language in a particular claim (*id.* at 10). Arthrex makes no mention of the prosecution history in discussing its “consisting essentially of” position. This is not surprising as the prosecution history leaves no doubt that the “consisting essentially of” language was added to the claims to specifically exclude bioabsorbable materials, as explained in Mitek’s Opening Brief (Mitek Op. Br. at 10-12). Even Arthrex’s counsel recognized this when he analyzed the 446 Patent and its prosecution history before this case was filed (Ex. 14). The prosecution history reinforces Mitek’s position of what the “consisting essentially of” language excludes, namely, bioabsorbable materials as the first or second fiber-forming materials.

For the reasons set forth above and in Mitek’s Opening Brief, Mitek’s construction of “consisting essentially of” should be adopted.

III. MITEK’S CONSTRUCTION OF “PE” SHOULD BE ADOPTED

Arthrex does not deny that “PE,” which is indisputably an abbreviation for the chemical term “polyethylene,” is a term of art. And Arthrex never denies that the plain meaning of “PE” encompasses all kinds of polyethylene, including ultra high molecular weight polyethylene. Rather, to support its strained and indefinite construction of the “PE” recited in the 446 Patent claims as limited to “general purpose polyethylene,” Arthrex improperly relies on unreliable extrinsic evidence – a commercial marketing brochure. Further, Arthrex improperly tries to limit

the construction of “PE” by incorporating aspects of preferred embodiments described in the 446 Patent specification and by mischaracterizing arguments made by the 446 Patent applicants’ counsel during prosecution of their patent. As explained below, there is no merit to any of Arthrex’s arguments.

A. Reference to Proper Technical Dictionaries and Expert Testimony is Appropriate in Construing Terms of Art, Such as “PE”

Arthrex’s argument that Mitek has improperly relied on extrinsic evidence – technical dictionaries – in support of its construction of the technical term “PE” is without merit.

Claim construction involves the search for the ordinary and customary meaning of a claim term to a person of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). The Federal Circuit has endorsed reference to extrinsic evidence, such as technical dictionaries and expert testimony, to ascertain the meaning of technical terms to persons of skill in the art. *Id.* at 1317; *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, No. 05-1363, -1461, 2006 U.S. App. LEXIS 21036 at *29-30 (Fed. Cir. Aug. 17, 2006) (Ex.15); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004); *NTP, Inc. v. Research in Motion*, 418 F.3d 1282, 1283 (Fed. Cir. 2005).

Mitek submitted evidence of what the term “PE” would have meant to one of skill in the art at the time of the 446 Patent filing. It submitted the Declaration of Dr. Matthew Hermes and citations to a technical dictionary and a widely-referenced resource for standard nomenclature of polymers (Ex. 7 to Mitek Opening Br, and Tab C and D thereto).² Dr. Hermes stated in his declaration, *inter alia*:

² Mitek regrets an error, in Mitek’s Opening Brief and in Dr. Hermes’ Declaration, to designation of two exhibits appended to Dr. Hermes’ Declaration. The exhibit at Tab B to his Declaration is the Hunter Patent, and the exhibit at Tab D is Generic Source-Based Nomenclature for Polymers.

One of skill in the art would have known that “PE” means “polyethylene” and means all polymers made from ethylene. PE is the generic name for all types of PE, including ultra high molecular weight PE.

(*Id.* at ¶9). Arthrex has submitted no valid, contradictory evidence of the plain meaning of “PE” to one of skill in the art.

Curiously, although Arthrex argues that resort to extrinsic evidence is improper, it plucks the phrase “general purpose polyethylene” – its proposed construction for “PE” – out of a commercial marketing brochure (Arthrex Op. Br. at 14 and Ex. 3 thereto)³. Arthrex cites no authority suggesting that commercial marketing brochures (unlike technical dictionaries and expert testimony) are a proper source of extrinsic evidence for reference in claim construction.

Further, despite failing to explain just what “general purpose polyethylene” is, the cited brochure – which pertains to only one commercial brand of ultra high molecular weight PE – fails to establish that those of skill in the art at the time of the invention would have understood “PE” as excluding ultra high molecular weight PE. The fact that PE’s of different molecular weights may have been known to have some different properties does not mean that the term “PE” – or “polyethylene” – could not be used generically to encompass all types of PE.

B. Arthrex Invites Legal Error by Trying to Incorporate Extraneous Limitations from the Specification into the Definition of “PE”

Since the plain meaning of “PE” is not limited to polyethylene of a certain molecular weight, Arthrex tries to tacitly incorporate descriptions of preferred embodiments into the definition of “PE.” For example, without actually proposing to add the modifiers “lubricious” and “lacking in strength” to the construction of “PE,” Arthrex argues that the “PE” must have those properties, that ultra high molecular weight PE lacks those properties, and that, accordingly, “PE” cannot encompass ultra high molecular weight PE (Arthrex Op. Br. at 11-12).

³ Mitek objects to the marketing brochure as inadmissible hearsay. Its Motion to Strike is being filed separately.

Not only do these arguments fly in the face of Federal Circuit precedent prohibiting importation of limitations from the specification into the claims, they lack evidentiary support.

1. Descriptions of Preferred Embodiments May Not Be Incorporated Into the Claims

Although the words of a claim are generally given the ordinary and customary meaning that they would have to a person of ordinary skill in the art at the time of the invention, that person of ordinary skill is deemed to read the claim term in the context of the entire patent. *Phillips*, 415 F.3d at 1312-13. Though the specification may be used to interpret and limit claim scope, a court cannot read into the claims a limitation that appears in the specification, as in the description of a preferred embodiment, but not in the claim terms. *Id.* at 1323; *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 906 (Fed. Cir. 2005); *Intervet Am., Inc. v. Kee-Vet Labs, Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989).

The circumstances in which the Federal Circuit *has* approved of limiting claim terms to disclosed embodiments – for example, where the embodiment is disclosed *as being* the invention (as in *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 865-66 (Fed. Cir. 2004)) or where the patentee clearly disavows a broader construction (as in *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1343-44 (Fed. Cir. 2005)) – are absent here. Arthrex can point to no such limiting invention definitions or disavowals in the 446 Patent specification.

Arthrex wants to tacitly incorporate a numerical range into the definition of “PE” – a molecular weight less than “ultra high” molecular weight⁴ – based on a discussion in the 446 Patent of one aspect of a preferred embodiment. Yet, when a claim term is expressed in general descriptive words (such as “PE”), it should not ordinarily be limited to a numerical range that

⁴ According to Arthrex, “general purpose PE” (whatever that is) has a molecular weight in the range of 50,000 to several hundred thousand, whereas ultra high molecular weight PE has a molecular weight in the range of 1 to 5 million. (Arthrex Op. Br. at 14).

may appear in the written description. *Conoco*, 2006 U.S. App. LEXIS at *17-18 (Ex. 15). In *Conoco*, the Federal Circuit refused to limit the term “water-alcohol mixture” to a composition having at least 30% water as described in the specification because the specification was referring to a preferred embodiment of the invention and the numerical ranges were not used in a context meant to limit the claims. *Id.* Here, there is no mention of any molecular weight range for PE in the 446 Patent, and the properties Arthrex wants to attribute to the claimed “PE” are, as were the numerical limitations in *Conoco*, mentioned in terms of a preferred embodiment, and not used in a context meant to limit the claims. Arthrex’s efforts to incorporate limitations from the discussion of preferred embodiments must fail in view of the Federal Circuit’s precedent proscribing the rewriting of claims in this manner.

2. Arthrex Mischaracterizes the Patent Disclosure

In its effort to write a “lubricious-but-relatively weak” requirement into the description of the first fiber-forming materials in the 446 Patent claims, Arthrex tries to create the fiction that the 446 Patent disclosure teaches that the first fiber-forming materials must have these properties. But the specification is not so limiting.

Citing to the patent specification at column 2, lines 22-25, Arthrex claims that the patent teaches that while a braid made entirely of lubricious materials would make a highly pliable braid, such a braid would be relatively weak and unusable (Arthrex Op. Br. at 11). This argument is unfounded. The sentence on which Arthrex relies *does not state* that the first set of yarns all necessarily form highly pliable braids and *does not describe* the first fiber-forming materials as weak:

“[i]f fibers composed of *highly lubricous polymers* are used in the traditional manner, then a highly pliable braid *can* be prepared. However, *in most cases*, these braids will be relatively weak and unusable”

(Ex. 1 at 2:22-25) (emphasis added). Significantly, this sentence refers to braids of “highly lubricous polymers” and does not state that all permutations of the first set of yarns are all necessarily such “highly lubricous polymers.” Further, this sentence states that “highly pliable braids *can* be prepared,” not that *all* braids made from the materials are highly pliable. Also, the sentence says that “*in most cases*,” but not all cases, these braids will be relatively weak. Finally, this sentence only refers to some *braids* as being weak, not the braided *materials* as being weak. Indeed, the 446 Patent never describes the first fiber-forming materials as “weak” (Ex. 16 at ¶36).

In another attempt to try to read all forms of PE out of the claims and the 446 Patent specification, Arthrex makes the unsupported argument that the first fiber-forming materials are just for “pliability.” But Arthrex ignores the totality of the specification, which has much broader teachings:

- “heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which makeup the yarns” (Ex. 1 at 2:49-52);
- “it is possible to tailor the physical . . . properties of the braid by varying the type and proportion of each of the dissimilar fiber forming used” (*id.* at 2:58-62);
- in preferred embodiments the first fiber-forming materials can contribute other properties including “pliability,” “compliance” and “surface lubricity” (*id.* at 4:11-13).

Out of these broad teachings, without explanation, Arthrex picks one property, pliability.

Notably, the very sentence relies on (Arthrex Br. at 11) provides a range of *alternative* properties, namely “overall pliability, *or compliance, and surface lubricity*” (Ex. 1 at 4:12-13).

Arthrex provides no explanation for ignoring the other properties referenced for preferred, first set of yarns. Further, Arthrex inexplicably ignores the fact the listed properties are termed “preferred embodiments” indicating that other properties may be contributed (*id.* at 4:11). The

reasons are transparent. Arthrex knows that FiberWire's ultra high molecular weight PE is "lubricous" (Ex. 8. at 239:10-13) and improves "compliance"⁵ and "surface lubricity," just as the 446 Patent describes. In any event, Arthrex's arguments that ultra high molecular weight PE does not add to pliability are just wrong because, as a lubricous material, ultra high molecular weight PE helps fiber-to-fiber mobility as the suture is bent and therefore contributes to pliability (Ex. 16 at ¶41).

3. In Any Event, Ultra High Molecular Weight PE Is a Lubricious Material (and PET Is a Strong Material)

Even if it were appropriate to tacitly incorporate a "lubricity" limitation into the definition of the "first fiber-forming materials," doing so would not lead to an exclusion of ultra high molecular weight PE from the claims. Arthrex's own witnesses have conceded that ultra high molecular weight PE is a lubricious material! (Ex. 9 at 52:24-53:1; Ex. 8 at 239:10-13).

Don Grafton, who developed Arthrex's accused FiberWire suture, testified that he originally tried to make a suture solely of ultra high molecular weight PE, but that the material was so lubricious, it caused the suture to have poor knot security (poor strength) (Ex. 9 at 51:15-53:5). To address that deficiency, Mr. Grafton decided to braid the ultra high molecular weight PE with another polymer to impart strength to the braid. The material he chose was one of the claimed second set of yarns, PET (Ex. 17 at 53:8-55:10). When he tested the ultra high molecular weight PE/PET braid, he found that it had improved strength properties compared to the 100% ultra high molecular weight PE braid (*id.* at 53:20-54:5; 54:24-55:1). This ultra high molecular weight PE/PET braid is the commercial FiberWire product accused in this action.

⁵ Compliance has been defined by Arthrex's developer of FiberWire as: "surgical feel, tactile feel of the suture by the surgeon" (Ex. 17 at 19:18-21).

Arthrex must have “forgotten” how its own product was developed when it argued that ultra high molecular weight PE “simply is not the kind of material which must be balanced against strong materials to achieve an acceptable suture” (Arthrex Op. Br. at 12). To the contrary, Arthrex’s developer found that balancing ultra high molecular weight PE with PET (a strong material) led to an acceptable suture.⁶

In addition to erroneously suggesting that the 446 Patent requires the first set of yarns to be lubricious, Arthrex also erroneously suggests that the patent requires the first set of yarns to be “relatively weak” in relation to the second set of yarns (*id.* at 11-12). The patent does no such thing. Just because the patent may suggest that the first set of yarns should preferably be lubricious does not mean that they cannot also exhibit strength. PVDF and polypropylene (PP), which are among the materials listed in the group of first fiber-forming materials, are not “weak” (Ex. 16 at ¶¶36-37). And, as inventor Mark Steckel pointed out, many if not all of the polymers listed in the patent claims can be processed in high-, medium-, or low-strength form (Ex. 18 at 106:12-24). Indeed, like polyethylene, *polypropylene* (PP) is available in an ultra high molecular weight form (Ex. 16 at ¶37). Arthrex’s technical expert, Dr. Mukherjee, agrees that *polypropylene* in all of its forms would be encompassed by the recitation of “PP” in the 446 Patent (Ex. 8 at 296:17-297:13). It is just Arthrex’s litigation-induced position that *polyethylene* (PE) in all of its forms would not be encompassed.

⁶ Contrary to Arthrex’s assertion (Arthrex Op. Br. at 11), Mitek’s expert, Dr. Brookstein, *did not* acknowledge that ultra high molecular weight PE is stiff and not pliable. In his report, Dr. Brookstein merely acknowledged that Defendant Pearsalls’ witness, Mr. Hallet, had testified that he had made a 100% homogeneous ultra high molecular weight PE braid, but that Arthrex had requested a less stiff braid, so he made a heterogeneous braid of ultra high molecular weight PE and PET. (Arthrex Op. Br. Ex. 11 at ¶56). Note that the above-referenced testimony of Mr. Grafton, who developed the accused FiberWire braid, reflected that he decided to braid ultra high molecular weight PE with PET because the ultra high molecular weight PE was too lubricious.

The facts simply do not support Arthrex's "strong yarns/weak yarns" story or its attempts to rewrite the 446 Patent claims. A material such as ultra high molecular weight PE – which is strong but which is also, by the admission of Arthrex's own witnesses, lubricious – falls squarely within the description of the preferred first yarns in the 446 Patent *and* within the plain meaning of the term "PE" as used in the claims.

The bottom line is that the invention made by the patentees, and disclosed and claimed in their patent, pertains to "mechanically blending" multifilament yarns of different materials to achieve a suture that exhibits a combination of the outstanding properties attributable to each of the different materials. In one embodiment, it may be that the first material is lubricious and relatively weak while the second material is relatively strong, but nothing in the 446 Patent disclosure limits the claims to that particular embodiment. Arthrex's attempts to recast the invention, and rewrite the 446 Patent claims, must be rejected as it is contrary to the evidence and legally erroneous.

C. The Prosecution History Does Not Support Arthrex's Position

Arthrex also invites error in suggesting that counsel's statements made during prosecution of the 446 Patent before the Patent Office somehow support Arthrex's strained construction of "PE."

As noted in Mitek's Opening Claim Construction Brief, if statements made during prosecution are to serve as limiting claim scope, they must be clear and unmistakable disclaimers (Mitek Opening Br. at 19-20). *See also, NTP*, 418 F.3d at 1308-09 (arguments to examiner may only limit the claims if they contain "words or expressions of manifest exclusion or restriction representing a clear disavowal of claim scope"). The inventors and their counsel did not clearly and unmistakably disclaim *any* PE, including ultra high molecular weight PE, during prosecution of the patent. Arthrex is just wrong in suggesting otherwise.

Arthrex as much as concedes that the statements made by counsel during prosecution lack the “clarity” required of a disclaimer by finding the need to import additional verbiage in its “quotation” from the prosecution history. Note this quotation in Arthrex’s brief, in which the bracketed language *is not in the original quote but was added by Arthrex*:⁷

“[E]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are (sic) presented by the Burgess application], one would inevitably design an unacceptable suture.”

(Arthrex Op. Br. at 6). When Arthrex’s convenient bracketed addition to the prosecution history statement is removed, it is apparent that the only clear and unmistakable statement being made by counsel was that one looking to design a suture would not find fishing line art to be helpful or analogous:

“Even if he did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture.”

(Ex. 3 at DMI000196-197). This statement was made in the context of a broader argument focusing on the dissimilarities in property requirements between sutures and fishing lines, so that “there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines” (*id.* at DMI000195-196). The statement (modified and) relied upon by Arthrex is no clear and unmistakable disavowal of the use of ultra high molecular weight PE in a suture.

Further, Arthrex does not explain how any arguments made by counsel in the August 1992 amendment could be deemed a limitation on the claim term “PE,” *when the term “PE” did not even appear in the claims being examined at that time*. The claims under rejection in the July 1992 Office action – in response to which the Amendment on which Arthrex relies was filed -- were Claims 21-24. These claims did not recite specific polymers for the first and second

⁷ Even the unbracketed portion of the statement is not an accurate quote from the prosecution history. *See* Ex. 3 at DMI000196-197.

fiber-forming materials; they did not recite “PE” (Ex. 3 at DMI000033-035; DMI000189-190). Counsel’s statement cannot be deemed to have clearly and unmistakably disclaimed a certain type of “PE” when the claims being argued at the time did not even expressly recite “PE.” *See, Purdue Pharms. L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136-1137 (Fed. Cir. 2006) (improper to imbue claims with specific requirements if nothing in the claim language requires such a limitation).

For all of the foregoing reasons, Arthrex’s limiting construction of “PE” should be rejected, and the plain-meaning construction proposed by Mitek should be adopted.

IV. CONCLUSION

Mitek requests an Order adopting its construction of the disputed claim terms.

Dated: September 1, 2006

DEPUY MITEK, INC.,
By its attorneys,
/s/ Erich M. Falke
Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

Daniel J. Gleason (BBO #194900)
Michelle Chassereau Jackson (BBO
#654825)
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of **DEPUY MITEK'S BRIEF IN RESPONSE TO ARTHREX'S CLAIM CONSTRUCTION BRIEF RE: MITEK'S HUNTER PATENT -- U.S. PATENT NO. 5,314,446** was served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro
1825 Eye Street, NW
Washington, DC 2006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: September 1, 2006

/s/ Erich M. Falke
Erich M. Falke

EXHIBIT 14

Tamburo, Salvatore

From: Soffen, Stephen
Sent: Tuesday, December 09, 2003 7:08 PM
To: 'jschmieding@arthrex.com'
Cc: 'dgrifton@arthrex.com'
Subject: Ethicon patent - FiberWire



us-5147400.pdf
(992 KB)



us-4052988.pdf
(723 KB)



DSMDB-1702667-v1
-A8130.0008 in...

John,

Attached is a memo prepared by Peter regarding the Patent Office file history of the Ethicon patent.

We will try to contact Mr. Ellis again tomorrow morning.

Steve

DEPUY MITEK
EXHIBIT 201
04cv12457

ARM 24341

"Confidential -
Outside Attorneys'
Eyes Only

MEMORANDUM

TO: Stephen A. Soffen
FROM: Peter F. McGee
DATE: December 9, 2003
RE: A8130.0008 - File Wrapper History of U.S. Pat. No. 5,314,446 to Hunter (Ethicon)

We reviewed the prosecution history for the Ethicon '446 patent.

Claim 1 as originally filed used open-ended "comprising" language.

Notably, Ethicon amended claim 1 during prosecution to include the closed language "consisting essentially of" to overcome rejections based on U.S. Pat. No. 5,147,400 to Kaplan et al., and U.S. Pat. No. 4,052,988 to Doddi et al.

Claim 1 was determined to be allowable after it was amended to include limitations to a first set of yarns made of a fiber-forming material selected from the group consisting of PRFE, FEP, PFA, PVDF, PETFE, PP, and PE, and a second set of yarns made of a fiber-forming material selected from the group consisting of PET, nylon, and aramid. Ethicon argued that the recited materials are all "non-bioabsorbable," and consequently distinguished over the prior art to Kaplan et al. (copy attached), which discloses suture sheaths containing bioabsorbable yarn. Amended claim 1 also distinguished over Doddi et al. (copy enclosed), which describes multifilament yarns composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives.

ARM 24342

Silk is an absorbable suture material and is not included in the two sets of yarn materials recited in amended claim 1. Consequently, the inclusion of silk in FiberWire, whether in place of polyethylene or in addition to polyethylene, will definitely avoid infringement of the Ethicon '446 patent.

ARM 24343

- 2 -

**"Confidential -
Outside Attorneys'
Eyes Only"**

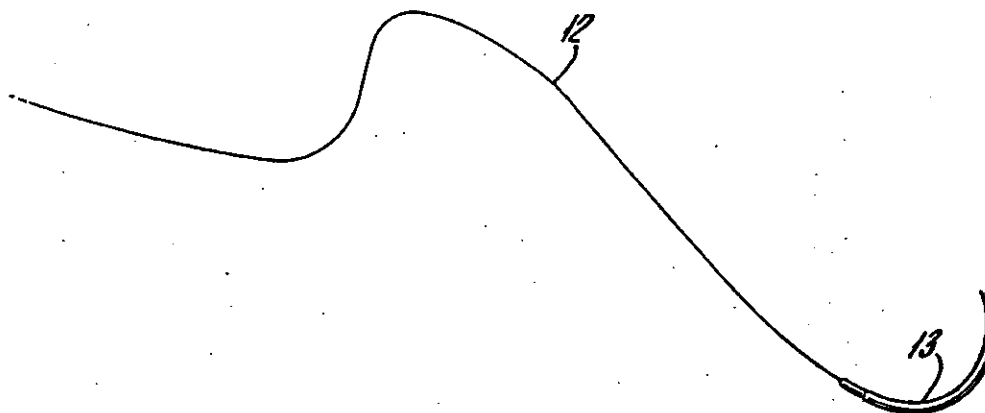
United States Patent [19][11] **4,052,988****Doddi et al.****BEST AVAILABLE COPY**[45] **Oct. 11, 1977**[54] **SYNTHETIC ABSORBABLE SURGICAL
DEVICES OF POLY-DIOXANONE**[75] **Inventors:** Namassivaya Doddi; Charles C.
Versafelt, both of Somerville; David
Wasserman, Springfield, all of N.J.[73] **Assignee:** Ethicon, Inc., Somerville, N.J.[21] **Appl. No.:** 648,236[22] **Filed:** Jan. 12, 1976[51] **Int. Cl.²** A61L 17/00[52] **U.S. Cl.** 128/335.5; 3/1;
128/92 B; 128/92 D; 260/78.3 R[58] **Field of Search** 128/335.5, 92;
260/78.3; 3/1[56] **References Cited****U.S. PATENT DOCUMENTS**

3,063,967	11/1962	Schultz	260/78.3
3,063,968	11/1962	Schultz	260/78.3
3,190,858	6/1965	Cox et al.	260/78.3
3,297,033	1/1967	Schmitt et al.	128/335.5

3,636,956	1/1972	Schneider et al.	128/335.5
3,645,941	2/1972	Snapp et al.	260/78.3
3,867,190	2/1975	Schmitt et al.	128/335.5 X
3,960,152	6/1976	Augurt et al.	128/335.5

OTHER PUBLICATIONSPalomaa et al.—Ber. Deut. Chem. Gesellsch., vol. 66B,
pp. 1629–1632 (1933).*Primary Examiner*—Dalton L. Truluck*Attorney, Agent, or Firm*—Wayne R. Eberhardt[57] **ABSTRACT**

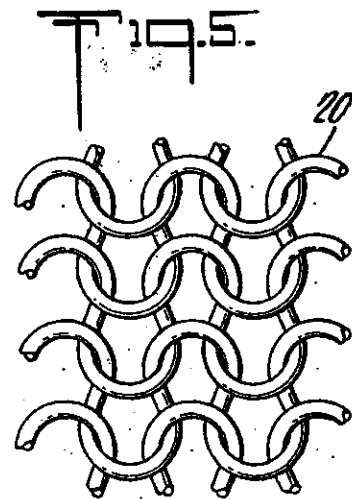
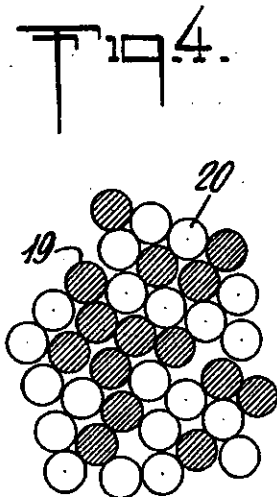
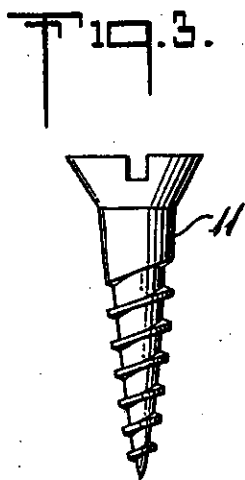
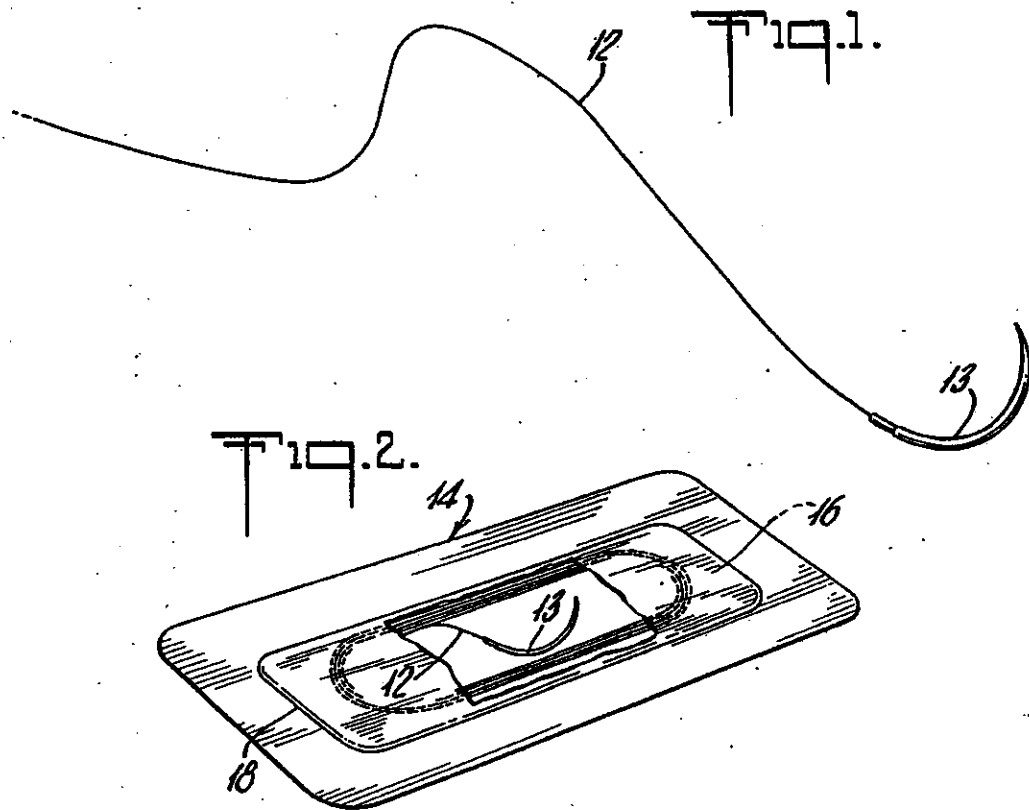
Synthetic absorbable sutures and other surgical devices are prepared from polymers of p-dioxanone and 1,4-dioxepan-2-one, and alkyl substituted derivatives thereof. Monofilament sutures of oriented fibers are characterized by good tensile and knot strength and a high level of flexibility and softness. The sutures have good in vivo strength retention and are slowly absorbed without significant tissue reaction.

39 Claims, 5 Drawing Figures**ARM 24344**

U.S. Patent

Oct. 11, 1977

4,052,988



ARM 24345

4,052,988

SYNTHETIC ABSORBABLE SURGICAL DEVICES OF POLY-DIOXANONE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to synthetic absorbable sutures, and more particularly, to synthetic absorbable sutures comprising extruded and oriented filaments of polymers of p-dioxanone or 1,4-dioxepan-2-one.

2. Description of Prior Art

Absorbable suture materials have traditionally been natural collagenous materials obtained from sheep or beef intestine, commonly known as catgut. More recently, it has been proposed to manufacture synthetic absorbable sutures from polyesters of hydroxycarboxylic acids, notably polylactide, polyglycolide, and copolymers of lactide and glycolide. Such synthetic absorbable sutures are described in U.S. Pat. Nos. 3,636,956, 3,297,033 and elsewhere in the literature.

Among the requirements of an ideal absorbable suture are that it should have good handling properties, should approximate and hold tissue for proper healing with minimal tearing and tissue damage, should have adequate straight tensile and knot strength, should be controllably uniform in properties including dimensional stability within the body, should be sterilizable, should be absorbable by living tissue, preferably at a constant rate regardless of the place in the body or the condition of the patient, without causing such unfavorable tissue reactions as walling off, granuloma formation, excessive edema, etc., and finally should be capable of being properly and easily tied into surgical knots.

While multifilament sutures manufactured from polymers of lactide and glycolide fulfill the above requirements to a large degree, monofilament sutures of these materials are considerably less flexible than catgut and these synthetic sutures are accordingly generally limited to a multifilament, braided construction. Sutures of glycolide polymers are also not suitable for sterilization by radiation without suffering severe degradation of physical properties.

The present invention provides synthetic absorbable sutures having a high degree of softness and flexibility which allows the sutures to be used in monofilament form. The sutures can also be sterilized with cobalt 60 radiation without serious loss of suture strength. It is accordingly an object of the present invention to provide synthetic absorbable sutures having unique and desirable properties not available with the sutures of the prior art.

We have discovered that polymers of p-dioxanone and 1,4-dioxepan-2-one prepared from monomers of very high purity can be melt extruded into pliable, monofilament fibers which are slowly absorbed in animal tissue without significant adverse tissue reaction. The fibers have good tensile and knot strength and good in vivo strength retention, and can be sterilized with cobalt 60 without serious loss of these properties.

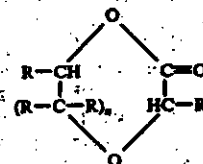
Polymers of p-dioxanone and fibers extruded therefrom have been known in the art. U.S. Pat. Nos. 3,063,967 and '968 for example, describe the polymerization of p-dioxanone and the preparation of films and fibers therefrom. The low tensile strength of fibers prepared in accordance with the teachings of these references, however, make these fibers generally unsuitable for use as surgical sutures. Moreover, there was no appreciation in these references of the absorbability of such

fibers which were reported to be resistant to the effects of saline and distilled water.

Other references dealing with the polymerization of p-dioxanone include, but are not limited to, U.S. Pat. Nos. 3,190,858, 3,391,126 and 3,645,941 which disclose various catalysts for the polymerization of lactones such as p-dioxanone, and U.S. Pat. No. 3,020,289 which describes the polymerization of p-dioxanone in the presence of sulfuric acid. None of these references suggest polymers of p-dioxanone or 1,4-dioxepan-2-one for use in the preparation of synthetic absorbable sutures in accordance with the present invention.

SUMMARY

Synthetic absorbable sutures are prepared from polymers of monomers having the formula:



wherein R' and each R are hydrogen, methyl or ethyl and n is 1 or 2, provided that when n is 2, at least two R groups are hydrogen.

Polymers prepared by the polymerization of very pure monomers are melt extruded into filaments suitable for use as synthetic absorbable sutures. The filaments are characterized by high tensile and knot strength, good strength retention in vivo, and a Young's modulus of less than about 600,000 psi corresponding to a high degree of softness and flexibility.

DESCRIPTION OF DRAWINGS

FIG. 1 is a perspective view of a needle-suture combination;

FIG. 2 is a perspective view of a suture-needle combination within a hermetically sealed container;

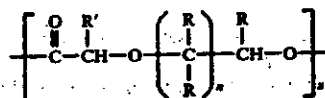
FIG. 3 illustrates a screw machined from the polymer of the present invention;

FIG. 4 is a cross-sectional view of a composite yarn containing filaments of different composition and;

FIG. 5 is a plan view of a surgical fabric knitted from fibers of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Polymers of the present invention are comprised of units having the general formula:

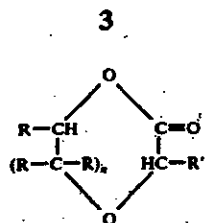


wherein R' and R are individually hydrogen, methyl, or ethyl, n is 1 or 2 provided that when n is 2 at least two R groups are hydrogen, and x is the degree of polymerization resulting in a fiber forming polymer.

The polymer is conveniently prepared from highly purified monomer, i.e., monomer of at least about 98 percent purity, having the formula:

ARM 24346

4,052,988



wherein R, R' and n are as defined above. When n is 1, the monomer is preferably p-dioxanone, methyl-p-dioxanone, or dimethyl-p-dioxanone. When n is 2, the monomer is preferably 1,4-dioxepan-2-one.

A particularly preferred monomer is p-dioxanone, and the following description and examples which are presented by way of illustration are directed primarily to the preparation and polymerization of that monomer, it being understood that certain variations may apply to other monomers and polymers encompassed by the above formula as will be readily apparent to those skilled in the art. Para-dioxanone monomer is conveniently prepared by reacting ethylene glycol, metallic sodium, and chloroacetic acid as hereinafter described in detail. The resulting monomer is preferably purified to 99+ % purity by multiple distillations and recrystallizations. We have discovered that high monomer purity is necessary to obtain a high molecular weight polymer and ultimately, a fiber of good tensile and dry knot strength.

The purified monomer is polymerized at a temperature of 20° to 130° C, most preferably above 75° C, in the presence of an organometallic catalyst as hereinafter described in detail to obtain a high molecular weight polymer of p-dioxanone characterized by an inherent viscosity of at least about 0.50 measured as a 0.1% solution in tetrachloroethane at 25° C, and a crystallinity of at least about 20% as determined by X-ray diffraction.

The polymer is melt extruded through a spinneret in a conventional manner to form one or more filaments which are subsequently drawn about 4x to 6x in order to achieve molecular orientation and improve tensile properties. The resulting oriented filaments have good tensile and dry knot strength and good in vivo strength retention.

To further improve dimensional stability and tensile strength retention, the oriented filaments may be subjected to an annealing treatment. This optional annealing treatment consists of heating the filaments to a temperature of from about 50° to 105° C, most preferably from about 50° to 80° C while restraining the filaments to prevent any substantial shrinkage. The filaments are held at the annealing temperature for a few seconds to several days or longer depending on the temperature and processing conditions. In general, annealing at 50° to 80° C for up to about 24 hours is satisfactory for p-dioxanone. Optimum annealing time and temperature for maximum improvement in fiber in vivo strength retention and dimensional stability is readily determined for each fiber composition.

Since the function of a suture is to join and hold severed tissue until healing is well along, and to prevent separation as a result of movement or exercise, a suture must meet certain minimum standards of strength. It is particularly important that strength be maintained when knots are tied and during the actual procedure of drawing tight a suitable knot. Oriented filaments of the present invention are characterized by a straight tensile strength of at least about 40,000 psi and a knot strength of at least about 30,000 psi, although significantly higher

strengths are possible as will be apparent from the following examples.

The preparation of high molecular weight oriented filaments of poly-p-dioxanone and other polymers of the present invention is further illustrated by the following examples where all percentages are by weight unless otherwise noted.

EXAMPLE I

A. Preparation of p-dioxanone

Metallic sodium is dissolved in a large excess of ethylene glycol to obtain a glycolate which is further reacted with about 0.5 mols of chloroacetic acid per mole of sodium to yield the sodium salt of the hydroxy acid. Excess ethylene glycol and by-products of the reaction are removed by distillation and by washing with acetone. The sodium salt is converted to the free hydroxy acid by the addition of hydrochloric acid, and the resulting sodium chloride is removed by precipitation with ethanol followed by filtration.

The hydroxy acid filtrate is slowly heated up to about 200° C, preferably in the presence of MgCO₃, to remove alcohol and water by distillation. Upon further heating at atmospheric pressure the p-dioxanone is formed and distills over at a head temperature of between about 200°-220° C. The purity of the crude dioxanone product is generally about 60-70 percent as determined by gas chromatography and yields are in the order of 50 to 70 percent.

The crude p-dioxanone is further purified to about 98 percent by redistillation, and finally purified to 99+ % by multiple crystallizations and/or distillation.

B. Polymerization of p-dioxanone

Highly purified p-dioxanone is polymerized in the presence of an organometallic catalyst such as diethyl zinc or zirconium acetylacetonate to obtain high molecular weight, fiber forming polymers according to the following typical procedure.

0.1 M (10.2 g) of dry, 99+ % pure p-dioxanone monomer is weighed into a dry flask under an inert atmosphere of dry nitrogen and 0.36 ml of 0.138M diethyl zinc in heptane are added. The monomer to catalyst ratio is calculated as 2000 : 1. After completely mixing the catalyst and monomer, the flask is swirled at intervals over a period of about one hour or less at room temperature until initiation and polymerization is evident by the occurrence of gelation. The flask is then connected to a vacuum of about 14 inches of Hg. The sealed flask is maintained at 80° C in a constant temperature bath for about 72 hours to complete the polymerization. The resulting polymer is characterized by an inherent viscosity I.V. of 0.70 measured on a 0.1% solution of polymer in tetrachloroethane at 25° C, a glass transition temperature T_g of -16° C, a melting temperature T_m of 110° C, and a crystallinity of 37 percent.

In the polymerization procedure, the initial one hour hold time for polymerization initiation is required only when using volatile catalysts which would be lost if the polymerization mixture was immediately placed under vacuum. When nonvolatile catalysts such as zirconium acetyl acetonate are used, this hold time may be omitted and the polymerization reaction mixture placed under vacuum immediately following addition and mixing of catalyst. As a further alternative, the entire polymeriza-

ARM 24347

4,052,988

5

tion reaction may be conducted under an inert atmosphere at atmospheric pressure.

C. Polymer Extrusion

The polymer obtained in the preceding step is thoroughly dried and melt extruded through a spinnerette using conventional textile fiber spinning procedures to obtain one or more continuous monofilament fibers suitable for use as synthetic absorbable sutures. The spun filaments are drawn about 5x at a temperature of about 43° C to increase molecular orientation and enhance physical properties, particularly tensile strength. The drawn monofilaments having a diameter of about 11 mils corresponding to a size 2-0 suture are characterized by an inherent viscosity of 0.64, a crystallinity of 30 percent, a straight tensile strength of 36,600 psi, an elongation of 99.4 percent, and a knot strength of 31,900 psi.

EXAMPLE II

The method of Example I was repeated using 0.13 ml of zirconium acetyl acetate catalyst (7500 : 1 monomer to catalyst ratio) in the polymerization reaction. Properties of polymer and fiber were as follows:

Polymer

I.V.: 0.71
Tg: -16° C
Tm: 111° C
Crystallinity: 49%

Fiber

I.V.: 0.57
Tensile Strength: 38,600 psi
Elongation: 88.5 percent
Knot Strength: 32,300 psi

EXAMPLE III

Polydioxanone polymers were prepared in accordance with the polymerization method of Example I using 0.20 ml of zirconium acetyl acetate catalyst (5000 : 1 monomer to catalyst ratio) and a polymerization temperature of 90° C. Polymer properties were as follows:

I.V.: 0.65
Tg: -19° C
Tm: 109° C
Crystallinity: 35%

EXAMPLE IV

The method of Example III was repeated using 0.50 ml of zirconium acetylacetate catalyst. (2000 : 1 monomer to catalyst ratio). Polymer properties were as follows:

I.V.: 0.59
Tg: -17° C
Tm: 111° C
Crystallinity: 44%

EXAMPLE V

The method of Example I was repeated at a monomer to catalyst ratio of 4000 : 1 and with a polymerization reaction of three days at 80° C. The resulting polymer had an inherent viscosity of 0.86 and crystallinity of 30 percent. Fibers extruded from the polymer and drawn 6x at 87° C had a diameter of 9 mils, a straight tensile strength of 65,100 psi, elongation of 47.6%, and knot strength of 46,400 psi.

6

EXAMPLE VI

The method of Example I was repeated using tetraoctylene glycol titanate as the polymerization catalyst. The monomer to catalyst ratio was 12,300 : 1 based on titanium content, and the polymerization reaction was maintained at 80° C for six days. The resulting polymer had an inherent viscosity of 0.86 and a crystallinity of 33 percent. Extruded filaments drawn 6x at 83° C had a diameter of 11 mils, a tensile strength of 55,600 psi, a dry knot strength of 48,800 psi, and a Young's modulus of 167,000 psi.

EXAMPLE VII

Two lots of polydioxanone were prepared according to the method of Example VI using a monomer to catalyst ratio of 26,700 : 1 and with a polymerization reaction of six days and 12 days. The resulting polymers had inherent viscosities of 0.81 and 0.84 respectively. The polymers were combined and extruded into fiber which, after drawing 6x, had the following physical properties.

Fiber Diameter: 9 mils
Tensile Strength: 70,600 psi
Elongation: 46.3

Dry Knot Strength: 50,300 psi
The monofilament fibers had a high degree of softness and pliability.

EXAMPLE VIII

In Vivo Absorption

Two 2 cm segments of monofilament fiber from Example I having a diameter corresponding to size 2-0 suture were implanted aseptically into the left gluteal muscles of 24 female Long Evans rats. The implant sites were recovered after periods of 60, 90, 120 and 180 days and examined microscopically to determine the extent of absorption.

After 60 days the suture cross sections were still transparent and intact. The tissue reactions were slight and most sutures were encapsulated with fibrous tissue. The sutures at this period remained birefringent under polarized light.

At 90 days the sutures were becoming translucent and had lost some of their birefringent properties. A few of the suture cross sections stained pink (eosinophilic) around the periphery and the edges were indistinct, indicating the onset of absorption. The tissue reactions generally consisted of a fibrous capsule and a layer of macrophages interposed between it and the suture surface.

At 120 days the sutures were translucent, most cross sections had taken on an eosinophilic stain; and the sutures appeared to be in the process of active absorption. The tissue reactions consisted of an outer layer of fibroblasts with an interface of macrophages several cell layers thick. Absorption at 120 days was estimated to be approximately 70 percent complete.

At 180 days, absorption of the suture was substantially complete. The incision healed with minimal adverse tissue reaction.

EXAMPLE IX

In Vivo Strength Retention

Segments of the sutures of several Examples were implanted in the posterior dorsal subcutis of female Long Evans rats for periods of 14, 21 and 28 days. The

ARM 24348

4,052,988

7

sutures were recovered at the designated periods and tested for straight tensile strength with the following results.

Test	Fiber	Implantation Time Days	Tensile Strength Pounds	Strength Retention %
a)	EX. I -	0	3.37	—
		14	1.46	43.4
		21	1.14	33.8
		28	—	—
b)	EX. I - (Sterilized) ¹	0	3.08	—
		14	1.16	37.6
		21	0.97	31.4
		28	0.70	22.9
c)	EX. VI - (Unannealed)	0	3.47	—
		14	2.27	65.3
		21	1.62	46.7
		28	1.53	44.1
d)	EX. VI - (Annealed) ²	0	6.47	—
		14	5.39	83.3
		21	4.87	75.3
		28	4.30	66.5
e)	EX. VI - (Annealed) ³	0	3.82	—
		14	2.07	54.0
		21	1.36	35.3
		28	0.68	17.8
f)	EX. V - (Sterilized) ¹	0	4.05	—
		14	2.77	68.4
		21	2.40	59.3
		28	2.15	53.2
g)	EX. V - (Sterilized) ³	0	3.45	—
		14	2.11	61.3
		21	1.36	39.3
		28	0.92	26.6

¹Sterilized with ethylene oxide at 30° C.

²Annealed under nitrogen 24 hours at 65° C.

³Sterilized with cobalt 60.

EXAMPLE X

Small quantities of polydioxanone polymer were prepared in accordance with the general method of Example I using chromatographically pure p-dioxanone monomer and diethyl zinc and tetraoctylene glycol titanate as catalysts. Polymer prepared with diethyl zinc catalyst at a monomer to catalyst ratio of 4,000 and with a polymerization reaction of three days at 80° C had an inherent viscosity of 1.18. Polymer prepared with tetraoctylene glycol titanate catalyst at a monomer to catalyst ratio of 12,250 and with a polymerization reaction of 6 days at 80° C had an inherent viscosity of 1.15. A second batch of high purity p-dioxanone monomer twice distilled in an annular still under a vacuum of 0.10-0.15 mm Hg was polymerized in the presence of tetraoctylene glycol titanate catalyst at a monomer to catalyst ratio of 13,300 and at 80° C for 6 days. The resulting polymer had an inherent viscosity of 2.26.

EXAMPLE XI

Preparation of Methyl-p-Dioxanone

Following the general procedure of Example I, metallic sodium was dissolved in a large excess of 1,2-propane diol and chloroacetic acid was added at 110°-115° C. Excess diol was removed by distillation and the sodium salt of the hydroxy acid converted to free acid by the addition of water and hydrochloric acid. Sodium chloride was precipitated by the addition of ethanol and removed by filtration. The resulting product was distilled in the presence of M_2CO_3 to remove excess alcohol and water and to recover crude methyl dioxanone monomer as a distillate at 196° to 202° C. After purification, the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

8

EXAMPLE XII

Preparation of Dimethyl-p-Dioxanone

The procedure of Example XI was repeated reacting metallic sodium with 2,3-butanediol and chloroacetic acid at about 130° C. Crude dimethyl dioxanone monomer was recovered from the distillation at 190° to 213° C. After purification the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

EXAMPLE XIII

Preparation of 1,4-dioxepan-2-one

The procedure of Example VI was repeated reacting metallic sodium with 1,3-propane diol and chloroacetic acid. Crude 1,4-dioxepan-2-one monomer was recovered from the distillation at 300° to 310° C. After purification, the monomer can be polymerized and extruded to form fibers suitable for use as absorbable sutures as described in Example I.

We have discovered that exceptionally high purity of p-dioxanone monomer is required to obtain polymers having a sufficiently high inherent viscosity to yield strong fibers upon extrusion. In general, the monomers are purified to 99+% by distillation and recrystallization prior to polymerization, and the resulting polymers have an inherent viscosity of at least about 0.50, and preferably 0.80 or higher measured as above described. As illustrated in Example X, polymers prepared from highly purified dioxanone have inherent viscosities well in excess of 1.10.

Drawn fibers of polydioxanone possess an unique combination of desirable properties. In particular, the monofilament fibers combine high tensile strength and knot strength with a pliability not to be found in any previous absorbable suture material, natural or synthetic. For example, the Young's modulus of the polydioxanone fiber of Example VI was 167,200 psi. In comparison, the Young's modulus for monofilament polyglycolide fibers and for 90/10 glycolide/lactide copolymer fibers is about 1 - 2 million psi, while that for moist catgut is about 350,000 psi. The low Young's modulus of polydioxanone makes this fiber particularly well suited for use as an absorbable monofilament suture, whereas prior synthetic absorbable sutures have largely been limited to braided, multifilament constructions which tend to be softer and more flexible than corresponding sizes of monofilament material. Monofilamented sutures are, of course, preferred for use in many surgical applications such as in ophthalmic procedures where smoothness of the suture surface is of particular importance.

The polymers of p-dioxanone of the present invention are also unique as compared with prior synthetic absorbable materials in that the sutures of these polymers can be sterilized by cobalt 60 radiation as well as by ethylene oxide. As illustrated in Example IX, while cobalt 60 sterilization results in some reduction in fiber strength and some increase in the in vivo rate of strength loss, the sterilized fiber nevertheless retains sufficient strength initially and for 28 days in vivo to make the fiber suitable for use in surgical procedures.

While the preceding examples have been directed to the preparation of homopolymers of p-dioxanone, methyl dioxanone, dimethyl dioxanone, and 1,4-dioxepan-2-one, these examples are for purposes of illustration only and are not limiting of the invention. Mixtures

ARM 24349

4,052,988

9

of these polymers, copolymers of two or more of the above enumerated monomers, and copolymers of these monomers with up to about 50% by weight of other copolymerizable monomers which produce non-toxic and absorbable polymers are likewise included within the present invention. For example, such copolymers of dioxanone with lactide and/or glycolide are useful in the preparation of absorbable sutures, and the physical and chemical properties of such sutures such as strength, stiffness, and rate of absorption can be controlled by varying the relative proportions of the monomer constituents. In addition, the copolymers may be prepared by random, block or graft polymerization techniques in order to obtain particular combinations of compositions and physical and chemical properties. In certain applications where the rate of absorption of polydioxanone is less than desired, copolymers of dioxanone with from about 5 to 25 percent or more glycolide having a faster rate of absorption may be preferred.

It is to be understood that inert additives such as coloring materials and plasticizers can be incorporated in the sutures. Any of a variety of plasticizers such as, for instance, glyceryl triacetate, ethyl benzoate, diethyl phthalate, dibutyl phthalate and bis 2-methoxyethyl phthalate can be used if desired. The amount of plasticizer may vary from 1 to about 20 percent or more based on the weight of the polymer. Not only does the plasticizer render the filaments even more pliable, but it also helps in spinning. As used herein, the term "inert" means materials that are chemically inert to the polymer, and biologically inert to living tissue, i.e., do not cause any of the adverse effects previously discussed.

Filaments of the present invention are adversely affected by moisture and are accordingly preferably packaged in a substantially moisture free environment and in hermetically sealed packages, a preferred form of which is shown in FIG. 2. In FIG. 2, there is shown a suture package 14 having disposed therein a coil of suture 12, one end of which is attached to needle 13. The needle and suture are positioned within a cavity 16 that is evacuated or filled with a dry atmosphere such as air or nitrogen. The package is fabricated of two sheets of aluminum foil or an aluminum foil-plastic laminate and heat sealed or bonded with adhesive at the skirt 16 to hermetically seal the cavity and isolate the contents of the package from the external atmosphere.

Filaments of the present invention may be used as monofilament or multifilament sutures, or may be woven, braided, or knitted either alone or in combination with absorbable fibers such as polyglycolide or poly (lactide-co-glycolide), or with non-absorbable fibers such as nylon, polypropylene, polyethyleneterephthalate, or polytetrafluoroethylene to form multifilament sutures and tubular structures having use in the surgical repair of arteries, veins, ducts, esophagi and the like.

Multifilament yarns that contain polymer filaments of the present invention together with nonabsorbable filaments are illustrated in FIG. 4 wherein the nonabsorbable fiber is represented by the hatched fiber cross section 19. In FIG. 4, the fibers 20 are extruded from homopolymer or copolymer compositions of the present invention as described above. The relative proportions of absorbable filaments 20 and nonabsorbable filaments 19 may be varied to obtain the absorption characteristic desired in the woven fabric or tubular implants. Methods of weaving and crimping vascular prostheses are described in U.S. Pat. 3,096,560.

10

Composite fabrics of absorbable and nonabsorbable materials fashioned by textile processes including weaving, knitting, and fabricating by the nonwoven felting of fibers are described in U.S. Pat. No. 3,108,357 and U.S. Pat. No. 3,463,158. Similar techniques may be used in the manufacture of surgical aids wherein nonabsorbable fibers are combined with absorbable fibers composed of the polymers of this invention. The surgical utility of "bicomponent filaments" containing absorbable and nonabsorbable components is described in U.S. Pat. No. 3,463,158, the teaching of which is incorporated herein by reference. Monofilaments of the polymers of the present invention may be woven or knitted to form an absorbable fabric having the structure illustrated in FIG. 5, useful surgically in hernia repair and in supporting damaged liver, kidney, and other internal organs.

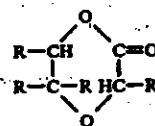
The products of the invention are useful in surgical applications where an absorbable aid or support is required, as for example, in the formation of surgical mesh, absorbable staples, artificial tendons, or cartilage material, and in other uses where a temporary aid during healing is needed. They may also be used to advantage in repairing hernias and in anchoring organs which have become loose.

The polymers of the present invention are also useful in the manufacture of cast films and other solid surgical aids such as scleral buckling prostheses. Thus, cylindrical pins, screws as illustrated in FIG. 3, reinforcing plates, etc., may be machined from the cast polymer having in vivo absorption characteristics depending upon the polymer composition and molecular weight.

Many different embodiments of this invention will be apparent to those skilled in the art and may be made without departing from the spirit and scope thereof. It is accordingly understood that this invention is not limited to the specific embodiments thereof except as defined in the appended claims.

We claim:

1. A sterile, synthetic absorbable suture comprising oriented fiber of a polymer of a monomer having the formula:



wherein R' and R are individually hydrogen, methyl or ethyl, said suture being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

2. A suture of claim 1 wherein R and R' are hydrogen and the monomer is p-dioxanone.

3. A suture of claim 2 wherein said polymer is characterized by an inherent viscosity greater than about 0.50 measured as 0.1% solution of polymer in tetrachloroethane at 25° C.

4. A suture of claim 3 comprising a homopolymer of p-dioxanone.

5. A suture of claim 1 comprising a polymer of methyl-p-dioxanone.

ARM 24350

4,052,988

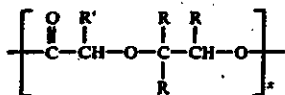
11

6. A suture of claim 1 comprising a polymer of dimethyl-p-dioxanone.

7. A suture of claim 1 comprising a copolymer of more than 50% by weight p-dioxanone and less than 50% by weight of at least one other monomer copolymerizable with p-dioxanone to an absorbable polymer.

8. A suture of claim 7 wherein said copolymer is of p-dioxanone and glycolide or lactide.

9. A sterile synthetic absorbable suture comprising oriented fiber of a polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said suture being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

10. A suture of claim 9 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1% solution of tetrachloroethane at 25° C.

11. A suture of claim 10 wherein the inherent viscosity of said polymer is at least 0.80.

12. A suture of claim 9 wherein said polymer is a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

13. A suture of claim 12 wherein said polymer is a copolymer of p-dioxanone and lactide or glycolide.

14. A suture of claim 9 wherein said polymer is a homopolymer of methyl-p-dioxanone or copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

15. A suture of claim 9 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

16. A suture of claim 1 having a surgical needle attached to at least one end thereof.

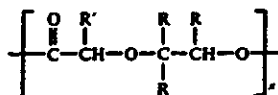
17. A needle and suture combination of claim 16 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

18. A suture of claim 9 having a surgical needle attached to at least one end thereof.

19. A needle and suture combination of claim 18 packaged in a sterile and dry environment within a hermetically sealed and substantially moisture impervious container.

20. A surgical prosthesis comprising a fabric manufactured at least in part from synthetic absorbable fibers of a polymer having units of the formula:

12



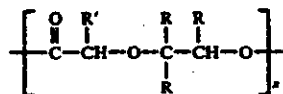
wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said fibers being dry to the extent of being substantially free of moisture, and characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

21. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of p-dioxanone or a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

22. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

23. A surgical prosthesis of claim 20 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

24. A surgical prosthesis comprising a solid surgical aid formed from an absorbable polymer having units of the formula:



wherein R' and R are individually hydrogen, methyl, or ethyl and x is the degree of polymerization resulting in a fiber forming polymer, said prosthesis being dry to the extent of being substantially free of moisture.

25. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1% solution of tetrachloroethane at 25° C.

26. A surgical prosthesis of claim 24 wherein said polymer is a copolymer of at least 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

27. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

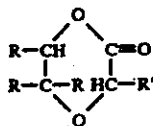
28. A surgical prosthesis of claim 24 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

ARM 24351

4,052,988

13

29. A method of closing a wound in living tissue which comprises approximating the edges of the wound with a synthetic absorbable suture consisting of at least one filament of a polymer of a monomer having the formula:



wherein R' and R are individually hydrogen, methyl or ethyl, said suture being at least partially embedded in the living tissue, and leaving said suture in said tissue until the embedded suture is absorbed during the healing process, said suture being characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

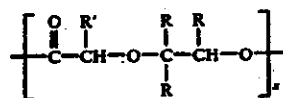
30. A method of claim 29 wherein R and R' are hydrogen and the monomer is p-dioxanone.

31. A method of claim 29 wherein the monomer is methyl-p-dioxanone.

32. A method of claim 29 wherein the monomer is dimethyl-p-dioxanone.

33. A method of closing a wound in living tissue which comprises approximating the edge of the wound with a synthetic absorbable suture consisting of at least one filament of a polymer having units of the formula:

14



wherein R' and R are individually hydrogen, methyl or ethyl, and x is the degree of polymerization resulting in a fiber forming polymer, said suture being at least partially embedded in the living tissue, and leaving said suture in said tissue until the embedded suture is absorbed during the healing process, said suture being characterized by a Young's modulus of less than about 600,000 psi with a correspondingly high degree of softness and flexibility, an initial straight tensile and knot strength of at least about 40,000 psi and 30,000 psi respectively, and substantially complete absorption in vivo within about 180 days.

34. A method of claim 33 wherein said polymer is a homopolymer of p-dioxanone having an inherent viscosity of at least 0.50 in a 0.1 percent solution of tetrachloroethane at 25° C.

35. A method of claim 34 wherein the inherent viscosity of said polymer is at least 0.80.

36. A method of claim 33 wherein said polymer is a copolymer of more than 50% by weight p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

37. A method of claim 36 wherein said polymer is a copolymer of p-dioxanone and lactide or glycolide.

38. A method of claim 33 wherein said polymer is a homopolymer of methyl-p-dioxanone or a copolymer of more than 50% by weight methyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

39. A method of claim 33 wherein said polymer is a homopolymer of dimethyl-p-dioxanone or a copolymer of more than 50% by weight dimethyl-p-dioxanone with less than 50% by weight of at least one other monomer copolymerizable to an absorbable polymer.

* * * * *

ARM 24352



US005147400A

United States Patent [19][11] Patent Number: **5,147,400****Kaplan et al.**[45] Date of Patent: **Sep. 15, 1992**[54] **CONNECTIVE TISSUE PROSTHESIS**

[75] Inventors: Donald S. Kaplan, Weston; John Kennedy, Stratford; Ross R. Muth, Brookfield, all of Conn.

[73] Assignee: United States Surgical Corporation, Norwalk, Conn.

[21] Appl. No.: 581,462

[22] Filed: Sep. 12, 1990

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 349,648, May 10, 1989, Pat. No. 4,990,158.

[51] Int. Cl.⁵ A61F 2/08

[52] U.S. Cl. 623/13; 623/1; 623/11; 623/66

[58] Field of Search 623/1, 13, 11

[56] **References Cited****U.S. PATENT DOCUMENTS**

3,463,158 8/1969 Schmitt et al. .
 3,537,280 11/1970 Garrou et al. .
 3,688,317 9/1972 Kurtz .
 3,805,300 4/1974 Tascon-Alonso et al. .
 3,878,565 4/1975 Sauvage .
 4,047,252 9/1977 Liebig et al. .
 4,187,558 2/1980 Dahlen et al. .
 4,193,138 3/1980 Okita .
 4,208,745 6/1980 Okita .
 4,229,838 10/1980 Mano .
 4,286,341 9/1981 Greer et al. .
 4,301,551 11/1981 Dore et al. .
 4,340,091 7/1982 Skelton et al. .
 4,350,731 9/1982 Siracusano .
 4,378,017 3/1983 Kosugi et al. .
 4,467,595 8/1984 Kramers .
 4,474,851 10/1984 Urry .
 4,483,023 11/1984 Hoffman, Jr. et al. .
 4,517,687 5/1985 Liebig et al. .
 4,530,113 7/1985 Matterson .
 4,584,722 4/1986 Levy et al. .
 4,610,688 9/1986 Silvestrini et al. .
 4,621,638 11/1986 Silvestrini .
 4,624,256 11/1986 Messier et al. .

4,642,119 2/1987 Shah .
 4,663,221 5/1987 Makimura et al. .
 4,668,233 5/1987 Seedhom et al. .
 4,693,720 9/1987 Scharnberg et al. .
 4,713,070 12/1987 Mano .
 4,713,075 12/1987 Kurland .
 4,718,907 1/1988 Karwoski et al. .
 4,775,380 10/1988 Seedhom et al. .
 4,788,979 12/1988 Jarrett et al. .
 4,816,028 3/1989 Kapadia et al. .
 4,816,339 3/1989 Tu et al. .
 4,822,361 4/1989 Okita et al. .
 4,871,365 10/1989 Dumican .
 4,894,063 1/1990 Nashef .
 4,942,875 7/1990 Hlavacek et al. .
 4,990,158 2/1991 Kaplan et al. 623/1

FOREIGN PATENT DOCUMENTS

0169045 1/1986 European Pat. Off. .
 0202444 11/1986 European Pat. Off. .
 0239775 10/1987 European Pat. Off. .
 0241252 10/1987 European Pat. Off. .
 0334046 9/1989 European Pat. Off. .
 WO8400302 2/1984 PCT Int'l Appl. .
 8901320 2/1989 World Int. Prop. O. 623/13

OTHER PUBLICATIONS

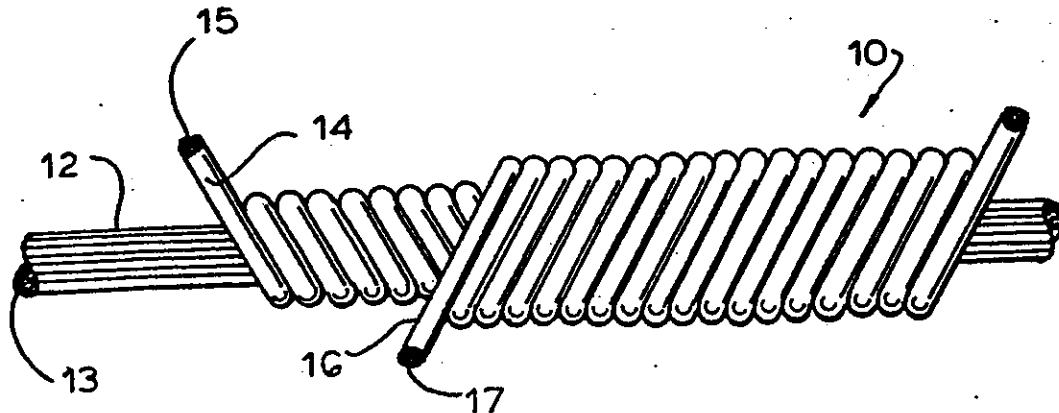
Am. J. Sports Med. 7,1: 18-22 (1979).
 Am. J. Sports Med. 8,6: 395-401 (1980).
 Am. J. Sports Med. 10,5: 259-265 (1982).
 Orthrop Trans 7: 174-175 (1983).
 Feagin, Jr., "The Crucial Ligaments", -Churchill Livingstone, New York (1988), pp. 540-544.

Primary Examiner—David Isabella
 Assistant Examiner—Debra S. Brittingham
 Attorney, Agent, or Firm—Thomas R. Bremer, Peter G. Dilworth, Rocco S. Barrese

[57] **ABSTRACT**

A semi-bioabsorbable connective tissue prosthesis, e.g., a replacement for the human anterior cruciate ligament, is provided whose stress-strain characteristics closely match those of the natural tissue.

58 Claims, 5 Drawing Sheets



ARM 24353

U.S. Patent

Sep. 15, 1992

Sheet 1 of 5

5,147,400

FIG. 1

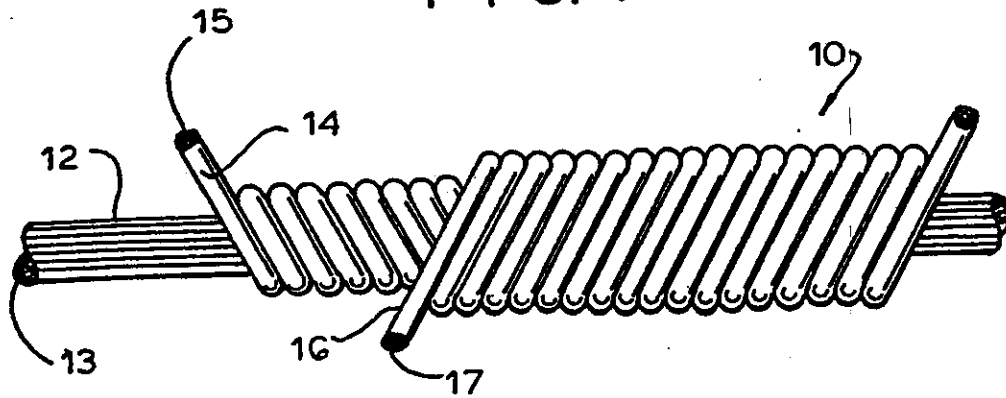


FIG. 2

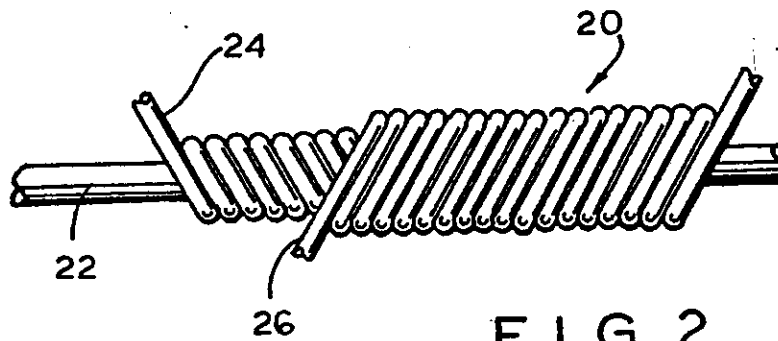
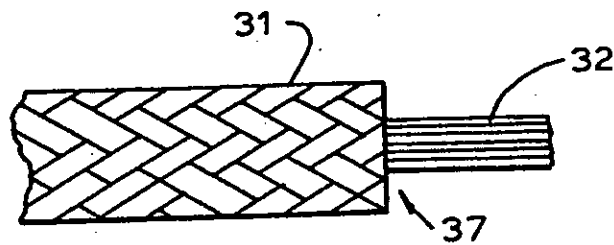


FIG. 5



ARM 24354

U.S. Patent

Sep. 15, 1992

Sheet 2 of 5

5,147,400

FIG. 3

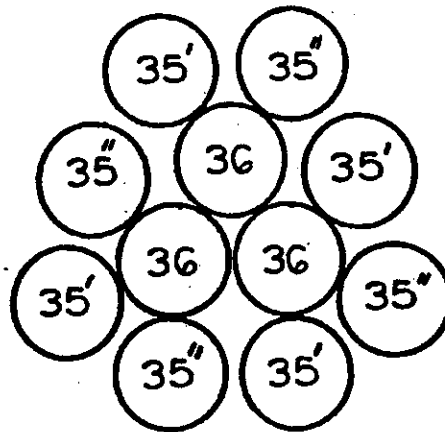
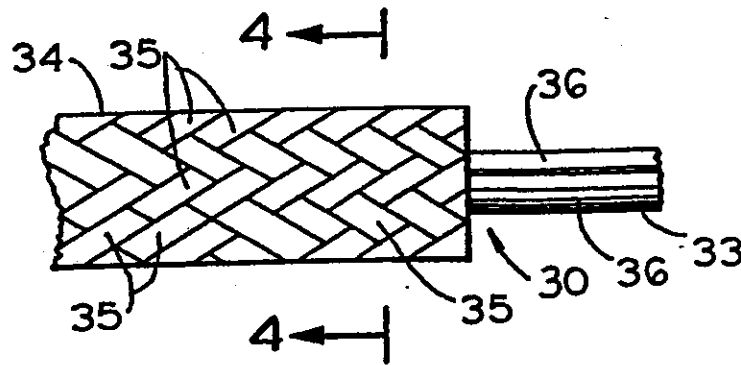


FIG. 4

ARM 24355

U.S. Patent

Sep. 15, 1992

Sheet 3 of 5

5,147,400

FIG. 6

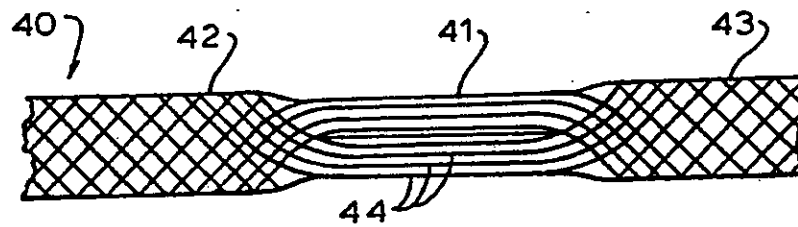
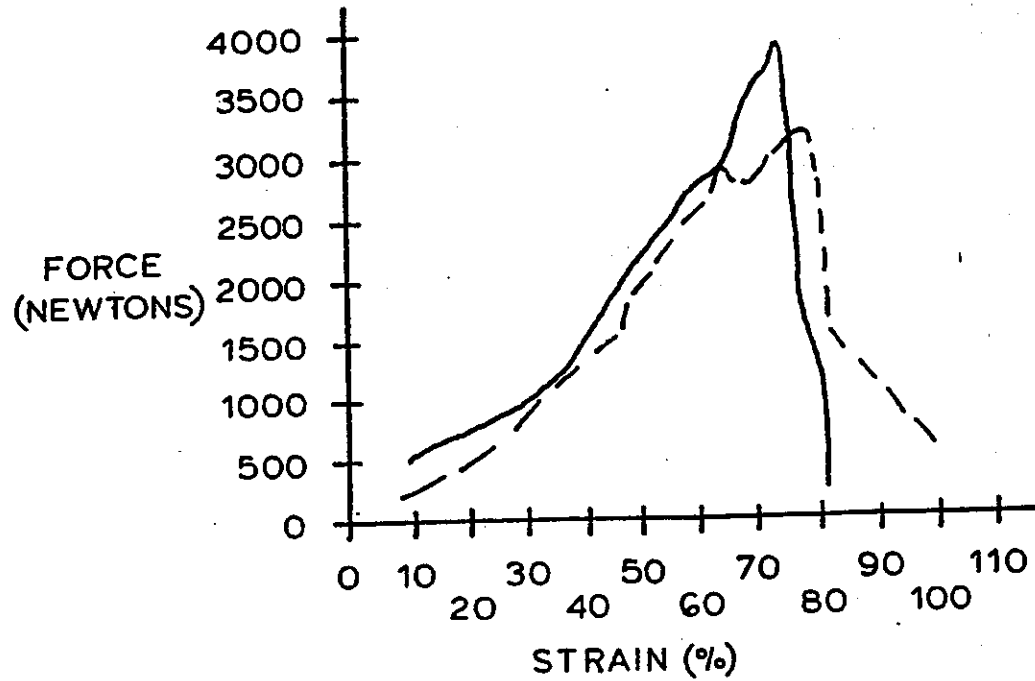


FIG. 7

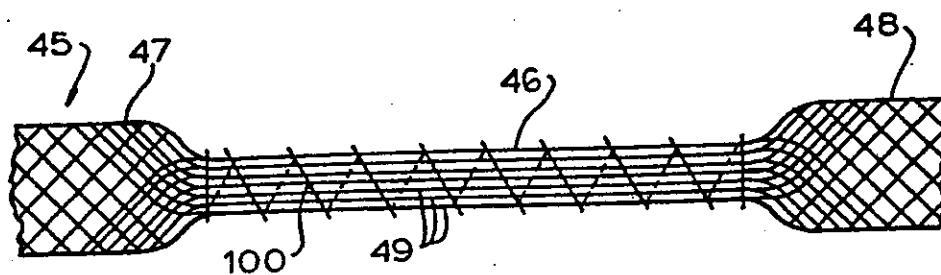


FIG. 8

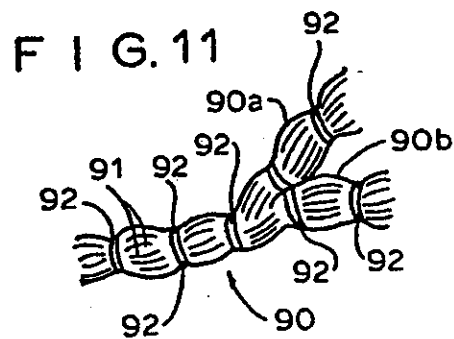
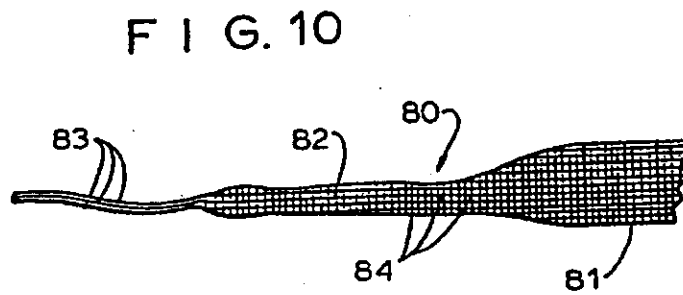
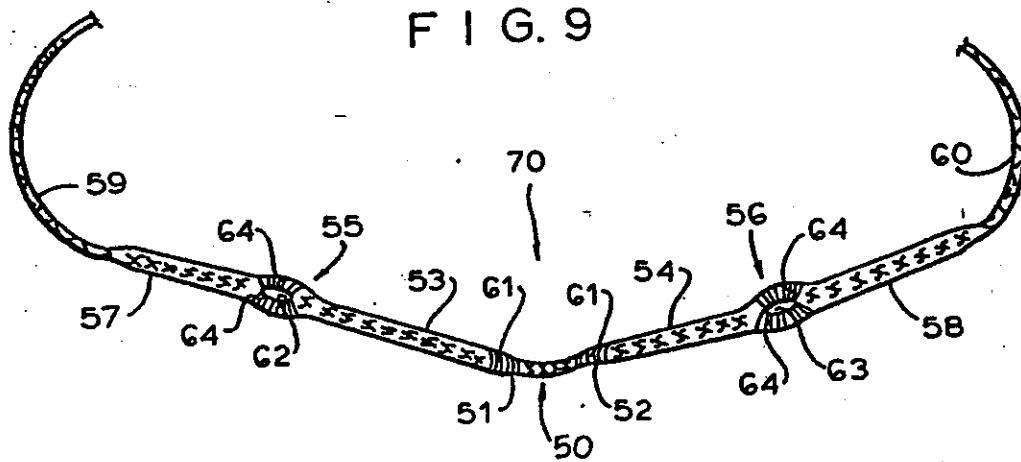
ARM 24356

U.S. Patent

Sep. 15, 1992

Sheet 4 of 5

5,147,400



ARM 24357

U.S. Patent

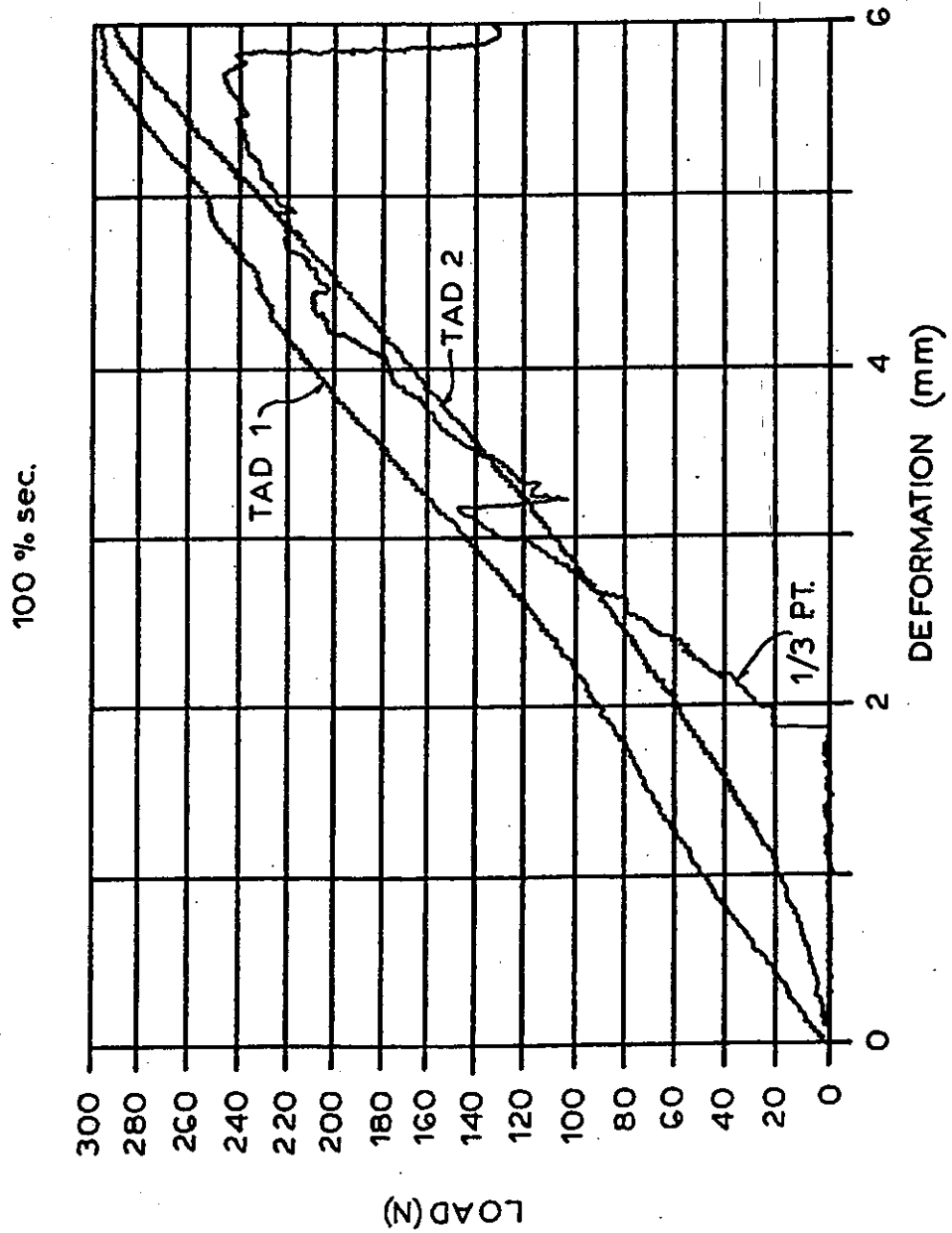
Sep. 15, 1992

Sheet 5 of 5

5,147,400

TENSILE TESTS

FIG. 12



ARM 24358

1

CONNECTIVE TISSUE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

The application is a continuation-in-part of commonly assigned, co-pending U.S. patent application Ser. No. 349,648, filed May 10, 1989, now U.S. Pat. No. 4,990,158.

BACKGROUND OF THE INVENTION

This invention relates to a connective tissue prosthesis and, in particular, to a biocompatible ligament or tendon prosthesis which closely approximates the biomechanical characteristics of the natural tissue to be replaced or augmented.

Numerous connective tissue materials and constructions have been proposed for use as temporary or permanent grafts in ligament and tendon repair. Feagin, Jr., Ed., *The Crucial Ligaments/Diagnosis and Treatment of Ligamentous Injuries About the Knee* (Churchill Livingstone, N.Y., 1988) describes a number of partially bioabsorbable materials which have been investigated for use as ligament grafts. In Chapter 33 of this publication (Rodkey, "Laboratory Studies of Biodegradable materials for Cruciate Ligament Reconstruction"), it is reported that while a 100 percent biodegradable ligament fabricated from polyglycolic acid (PGA) was found to be safe, strong, well-tolerated and provided stability for the repaired anterior cruciate ligament in dogs, its complete resorption within five weeks makes it unsuitable for use in prostheses intended for humans since a human ligament prosthesis must provide support over a much longer period of time. It is further reported that a study in dogs of the intraarticular use of a partially biodegradable ligament prosthesis possessing a Dacron (i.e., DuPont's polyethylene terephthalate (PET)) and PGA core and a separate outer sleeve woven from PGA and Dacron of a different percentage of composition gave disappointing results.

U.S. Pat. Nos. 4,792,336 and 4,942,875 describe a surgical device for repairing or augmenting connective tissue and comprising a plurality of fibers, in which the majority of the fibers are in a direction essentially parallel to the length of the device and can be either 100 percent bioabsorbable or can contain a nonabsorbable component. Additionally, sleeve yarns consisting completely of absorbable material wrap around these axial or warp yarns.

Biomedical Business International Report No. 7041 (Second Revision, May 1986), "Orthopaedic and Diagnostic Devices", pages 5-5 to 5-12, identifies a variety of materials which have been used in the fabrication of prosthetic ligaments including carbon fiber, expanded Teflon (i.e., DuPont's polytetrafluoroethylene), a combination of silicone and PET, polypropylene, polyethylene, nickel-chromium alloy fibers individually enclosed in synthetic textile or natural silk, carbon material coated with gelatin, polyester combined with PET fibers, bovine tissues, and others.

Other disclosures of ligament and tendon repair devices are provided, inter alia, in U.S. Pat. Nos. 3,805,300; 4,187,558; 4,301,551; 4,483,023; 4,584,722; 4,610,688; 4,668,233; 4,775,380; 4,788,979; and PCT Patent Publication No. WO 89/01320.

5,147,400

2

Chapter 33 (page 540) of the Feagin, Jr. publication referred to above identifies the characteristics of an ideal ligament prosthesis as follows:

- (1) it must be durable with adequate strength to withstand the extreme forces placed upon it, yet compliant enough to allow for repetitive motion without failure or excessive creep elongation;
- (2) it must be tolerated by the host with no antigenic or carcinogenic reaction;
- (3) if partially or completely biodegradable, the size of the individual fibers and the construction pattern must be appropriate to support and allow eventual reconstitution of the repaired structure with ingrowth of fibrous tissue that matures to normal or near normal collagen;
- (4) it must tolerate sterilization and storage; and
- (5) it should be easily implanted using surgical and potentially arthroscopic techniques.

The existence of so many different types of materials and devices for use in connective tissue repair, some of which have been identified above, bears testimony to the difficulty of meeting some, much less all, of the foregoing characteristics in a single prosthetic device.

SUMMARY OF THE INVENTION

It is a principal object of the invention to provide a semi-bioabsorbable or fully bioabsorbable connective tissue prosthesis, e.g., a ligament or tendon repair device, which exhibits the stress-strain properties of the natural tissue to be replaced or augmented.

It is a specific object of the invention to provide the foregoing connective tissue prosthesis as a structure formed from a composite yarn comprising a non-bioabsorbable core yarn surrounded by a bioabsorbable or semi-bioabsorbable cover or sheath yarn.

It is a further specific object of the invention to provide a connective tissue prosthesis formed from a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-bioabsorbable sheath yarn, so as to exhibit the stress-strain properties of natural tissue.

It is another specific object of the invention to provide a prosthetic replacement for a human anterior cruciate ligament which is based on the aforesaid structure, in particular, one fabricated from a yarn whose sheath yarn component is derived from a glycolide-lactide copolymer.

In keeping with these and other objects of the invention, there is provided a connective tissue prosthesis comprising:

- (a) a core made up of a first biocompatible composite yarn extending in the lengthwise direction; and
 - (b) a sheath surrounding the core and fabricated from a second biocompatible yarn,
- wherein the first composite yarn in the core (a) comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The second biocompatible yarn forming the sheath (b) may be the same as, or different from, the first composite yarn which forms the core (a). More specifically, the second biocompatible yarn may also comprise a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

Also in keeping with the above and other objects of the invention, a connective tissue prosthesis is provided which comprises a tubular component fabricated from

ARM 24359

5,147,400

3

composite yarn, the yarn comprising a biocompatible, nonbioabsorbable core yarn component surrounded by a biocompatible, bioabsorbable or semi-bioabsorbable sheath yarn component.

The foregoing connective tissue prostheses meet the Feagin, Jr. criteria, identified supra, to a surprising degree. Due to elasticity of the composite yarn core component and relative inelasticity of the composite yarn sheath component, the stress-strain characteristics of the connective tissue prostheses closely match those of the natural tissue which they replace and their resorption properties can be calibrated to maintain the functionality of the prostheses throughout the entire period of the tissue regeneration process. The prostheses of this invention are readily sterilizable, possess good storage stability when suitably protected from hydrolytic forces, and can be installed at a ligament, tendon, vascular, or tracheal repair site employing known surgical reconstruction techniques.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are enlarged isometric views of composite yarns which are utilized in the construction of the connective tissue prosthesis herein;

FIG. 3 is an enlarged isometric view of an alternative composite yarn utilized in the construction of the connective tissue prosthesis herein;

FIG. 4 is a schematic, cross-sectional view along line 4-4 of FIG. 3;

FIG. 5 represents a section of a ligament prosthesis manufactured from the composite yarn of FIG. 1 and suitable for use in the surgical reconstruction of the human anterior cruciate ligament;

FIG. 6 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 5 compared with the stress-strain characteristics of a natural ligament as reported in the literature;

FIG. 7 represents a section of a tubular ligament prosthesis manufactured from the composite yarn of the present invention and having an unbraided center section;

FIG. 8 represents a section of a tubular ligament prosthesis similar to FIG. 7 and additionally having the unbraided center section helically wrapped with a yarn;

FIG. 9 represents a section of a braided prosthesis manufactured from composite yarn of the present invention and modified in various fashion over the length thereof;

FIG. 10 represents a section of a tubular braided prosthesis manufactured from composite yarn of the present invention and provided with threading means;

FIG. 11 represents a section of a prosthesis manufactured from composite yarn of the present invention in which the prosthesis is branched; and

FIG. 12 is a plot of experimental data showing the stress-strain characteristics of the prosthesis of FIG. 7 compared with a canine patellar tendon.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, composite yarn 10 comprises a core yarn component 12 made up of a multiplicity of individual biocompatible, essentially non-bioabsorbable and preferably elastic filaments 13, advantageously provided with a slight to moderate twist, and a sheath yarn component 14 made up of a multiplicity of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 15 wound in a

4

first direction around the core and an external multifilamentous sheath yarn component 16, also made up of individual biocompatible, bioabsorbable or semi-bioabsorbable and preferably relatively inelastic filaments 17, wound in a second and opposite direction around sheath yarn component 14. For example, multifilamentous sheath yarn component 16 may comprise both absorbable and non-absorbable filaments 17. Generally, the filaments 13 of core yarn component 12 are substantially parallel.

Non-bioabsorbable core yarn component 12 functions to impart elasticity to composite yarn 10 and acts as a scaffolding during and after absorption of the bioabsorbable sheath. Bioabsorbable sheath yarn components 14 and 16 function to provide the composite yarn with relative inelasticity, tensile strength, and absorption characteristics which allow for desirable tissue ingrowth and incorporation of the composite yarn into the body structure. Sheath yarn components 14 and 16 each have a lengthwise axis which is non-perpendicular to the lengthwise axis of core component 12. While core yarn component 12 can be wrapped with a single layer of sheath yarn component, the illustrated arrangement of two layers of sheath yarn components 14 and 16 is generally preferred as this construction helps to give composite yarn 10 a balanced structure which resists crimping or kinking when used in the manufacture of a prosthesis such as shown in FIGS. 5 and 7-11.

Where, as shown in the embodiment of FIG. 1, at least two sheath yarn components are employed in the construction of the composite yarn, the composition, number and denier of the individual filaments, and braiding (if any) of these yarn components as well as their relative rates of bioabsorption can differ. For example, non-absorbable filaments may be combined with absorbable filaments to provide one or more semi-absorbable sheath yarn components. This capability for differential absorption can be advantageously exploited in a connective tissue prosthetic device in which the outermost sheath yarn component is absorbed by the body at a faster rate than the underlying sheath yarn component, or vice versa, thus resulting in a staged absorption of the sheath components of the composite yarn.

Core yarn component 12 must be essentially non-bioabsorbable, i.e., it must resist degradation when, as part of the connective tissue prosthesis of this invention, it is implanted in a body. The term "non-bioabsorbable" as used herein applies to materials which permanently remain within the body or at least remain in the body for a relatively long period of time, e.g., at least about two years. It is preferred to employ a core yarn material which is also elastic, i.e., a polymeric material which in filamentous form exhibits a relatively high degree of reversible extensibility, e.g., an elongation at break of at least about 30 percent, preferably at least about 40 percent and more preferably at least about 50 percent. Fiber-forming polymers which are both non-bioabsorbable and elastic, and as such preferred for use as the core yarn component herein, include fiber-forming polyolefins such as polyethylene homopolymers, polypropylene homopolymers, ethylene propylene copolymers, ethylene propylene terpolymers, etc., fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, polyether-polyester copolymers, and the like. Hytrel (DuPont), a family of copolyester elastomers based on (soft) polyether segments and (hard) polyester segments, and span-

ARM 24360

5,147,400

5

dex, an elastomeric segmented polyurethane, provide especially good results.

Hytrel is manufactured in various commercial grades by DuPont, such as Hytrel 4056, 5526, 5556 and 7246. Hytrel 5556 is especially suitable as the core component 12 of the composite yarn 10 when used to form a vascular graft, while Hytrel 7246 is well-suited for the core component 12 of the composite yarn 10 when used to form a ligament prosthesis or tendon augmentation device.

Several properties of the various Hytrel grades are presented in the table below:

	Hytrel Grade No. (Injection Molded at 23° C. for Testing)			
	4056	5526	5556	7246
Hardness in durometer points (ASTM Test No. D2240)	40	55	55	72
Flexural Modulus (ASTM Test No. D790)				
at -40° C. in MPa	155	930	930	2,410
at -40° F. in psi	22,500	135,000	135,000	350,000
at 23° C. in MPa	55	207	207	518
at 73° F. in psi	8,000	30,000	30,000	75,000
at 100° C. in MPa	27	110	110	207
at 212° F. in psi	3,900	16,000	16,000	30,000
ASTM Test No. D638				
(¹)Tensile Strength at Break,				
MPa	28.0	40.0	40.0	45.8
psi	4050	5800	5800	6650
(²)Elongation at Break, %	550	500	500	350
(³)Tensile Stress at 5% Strain,				
MPa	2.4	6.9	6.9	14.0
psi	350	1,000	1,000	2,025
(⁴)Tensile Stress at 10% Strain,				
Mpa	3.6	10.3	10.3	20.0
psi	525	1,500	1,500	2,900
Izod Impact (Notched) (ASTM Test No. D256, Method A)				
at -40° C. in J/cm	No Break	No Break	No Break	0.4
at -40° F. in ft-lbf/in	No Break	No Break	No Break	0.8
at 23° C. in J/cm	No Break	No Break	No Break	2.1
at 73° F. in ft-lbf/in	No Break	No Break	No Break	3.9
Resistance to Flex Cut Growth, Ross (Pierced), in Cycles to 100% cut growth (ASTM Test No. D1052)	> 1 × 10 ⁶	> 5 × 10 ⁵	> 5 × 10 ⁵	—
(⁵)Initial Tear Resistance, Die C (ASTM Test No. D1004),				
in kN/m	101	158	158	200
in lbf/in.	580	900	900	1,146
Melt Flow Rate in g/10 min. (ASTM Test No. D1238)	5.3	18	7.0	12.5
Test Conditions: Temperature, °C./Load, Kg	190/2.16	220/2.16	220/2.16	240/2.16
(⁶)Melting Point (ASTM Test No. D3418)				
in °C.	148	202	202	219
in °F.	298	396	396	426
Vicat Softening Point (ASTM Test No. D1525)				
in °C.	108	180	180	207
in °F.	226	356	356	405
Specific Gravity (ASTM Test No. D792)	1.16	1.20	1.20	1.25
Water Absorption, 24 hr. in % (ASTM Test No. D570)	0.6	0.5	0.5	0.3

(¹)head speed 50 mm/min. or 2 in./min.

(²)head speed 25 mm/min. or 1 in./min.

(³)specimens 1.9 mm or 0.075 in. thick.

(⁴)differential scanning calorimeter (DSC), peak of endotherm

Corresponding properties of other grades of Hytrel are available from DuPont.

If desired, the core yarn component can be provided with a nonabsorbable hydrophilic coating to improve its wettability by body fluids, e.g., synovial fluid. Hy-

6

drophilic coatings which are suitable for this purpose include polymeric materials such as the sparingly cross-linked poly(hydroxyethyl methacrylate) hydrogels disclosed in U.S. Pat. Nos. 2,976,576 and 3,220,960; hydrogels based on cross-linked polymers of n-vinyl lactams and alkyl acrylates as disclosed in U.S. Pat. No. 3,532,679; graft copolymers of hydroxyalkyl methacrylate and polyvinylpyrrolidone disclosed in U.S. Pat. No. 3,621,079, and many others.

Fiber-forming materials which are relatively inelastic are suitable for providing the sheath yarn component of composite yarn 10 provided such materials are fairly

rapidly bioabsorbed by the body, e.g., exhibiting a loss of tensile strength in from about 2 to about 26 weeks and total absorption within from about two to about fifty

ARM 24361

5,147,400

7

two weeks. It is to be understood, however, that the expression "relatively inelastic" does not preclude the presence of some minor degree of elasticity in the sheath yarn component, merely that it excludes a degree of elastic behavior as described in connection with the preferred type of core yarn component.

The sheath yarn component can be woven, braided or knitted in whole or in part and will ordinarily possess a relatively high tensile strength, e.g., a straight tensile strength of at least about 30,000 p.s.i., preferably at least about 60,000 p.s.i. and more preferably at least about 90,000 p.s.i.

Bioabsorbable, relatively inelastic fiber-forming polymers and polymer blends from which the sheath yarn component herein can be formed include those derived at least in part from such monomers as glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, ε-caprolactone, hydroxycaproic acid, etc., and various combinations of these and related monomers as disclosed, e.g., in U.S. Pat. Nos. 2,668,162; 2,703,316; 2,758,987; 3,225,766; 3,297,033; 3,422,181; 3,531,561; 3,565,077; 3,565,869; 3,620,218; 3,626,948; 3,636,956; 3,736,646; 3,772,420; 3,773,919; 3,792,010; 3,797,499; 3,839,297; 3,867,190; 3,878,284; 3,982,543; 4,047,533; 4,052,988; 4,060,089; 4,137,921; 4,157,437; 4,234,775; 4,237,920; 4,300,565; 4,429,080; 4,441,496; 4,523,591; 4,546,152; 4,559,945; 4,643,191; 4,646,741; 4,653,497; and, 4,741,337; U.K. Patent No. 779,291; D. K. Gilding et al., "Biodegradable polymers for use in surgery—polyglycolide/poly(lactic acid) homo- and copolymers: 1", *Polymer*, Volume 20, pages 1459-1464 (1979), and D. F. Williams (ed.), *Biocompatibility of Clinical Implant Materials*, Vol. II, ch. 9: "Biodegradable Polymers" (1981).

Sheath yarn components manufactured from polymers of high lactide or glycolide content, e.g., those in which at least about 75 percent of the monomeric units are derived from either glycolide or lactide, are preferred for the construction of the composite yarn of this invention. Polymers of high glycolide content tend to be absorbed more quickly than those possessing a high lactide content. Accordingly, the glycolide-based polymers may be preferred for the manufacture of a sheath yarn component providing the outermost sheath yarn(s) in a multiple sheath yarn component construction, the underlying internal sheath yarn(s) being manufactured from the more slowly absorbable lactide-based polymers. An especially preferred lactide-glycolide copolymer for forming the sheath yarn component of the composite yarn contains from about 70 to about 90, and preferably from about 75 to about 85 mole percent lactide monomer with the balance being provided by the glycolide monomer. Thus, for example, a sheath yarn component formed from a lactide-glycolide copolymer based on 80 mole percent lactide-20 mole percent glycolide is especially advantageous for constructing the composite yarn, and ultimately, the connective tissue prosthesis, of the present invention. The sheath yarn component, which is preferably braided around the core yarn component, may comprise a plurality of bioabsorbable fibers in turn comprising at least two different chemical compositions.

The deniers of core yarn component 12 and sheath yarn components 14 and 16 are not especially critical and those of commercially available yarns such as Vicryl (a glycolide/lactide copolymer suture available from Ethicon) and Dexon (a polyglycolide suture available from American Cyanamid) are suitably employed.

8

Preferably, the deniers are selected so as to provide a composite yarn having an overall denier of from about 40 to about 1200 and preferably from about 80 to about 500, the overall denier of the core and/or sheath yarn components being from about 20 to about 600 and preferably from about 40 to about 300. The deniers of individual filaments in the core and sheath yarn components of multifilamentous construction can vary widely, e.g., from about 0.2 to about 6.0 and preferably from about 0.4 to about 3.0. The base weight for a desired composite yarn will determine the size and weight of the component elements of the yarn. Composite yarn 10 possesses sufficient core material to impart, inter alia, a desired resiliency and sufficient sheath material to provide, inter alia, a desired tensile strength for a particular connective tissue prosthetic application. In general, the core component can represent from about 20 to about 80 percent, and preferably from about 30 to about 70 percent of the total weight of composite yarn 10. Optimum core and sheath component weights will naturally vary depending on the specific application and can be readily determined in a given case based on the desired physical properties of the prosthetic device without undue experimentation.

Methods and apparatus for covering core yarn components with sheath yarn components are well known and need not be described here in detail. In general, the sheath yarn components are wrapped about the core yarn component on a covering machine which includes a hollow spindle with rotating yarn supply bobbins supported thereon. The elastic core yarn component is fed through the hollow spindle and the elastic sheath yarn components are withdrawn from the alternate direction rotating supply bobbins and wrapped about the core yarn component as it emerges from the hollow spindle. The core yarn component is preferably under a slight tension during the covering procedure and the sheath yarn components are laid down in a side-by-side array. The number of wraps per inch will depend on the denier of the sheath yarn components but should be sufficient to cause the sheath yarn components to lay close to the core yarn component when tension on the latter is relaxed.

As desired, the filaments which comprise a sheath yarn component can be provided with no twist or with varying degrees of twist. Where the yarns are twisted, it can be advantageous to balance or equalize the twist in the final composite yarn structure. Thus, for example, in the embodiment of composite yarn 10 in FIG. 1, if sheath yarn component 14 has a given twist, sheath yarn component 16 should have an equivalent twist. Since sheath yarn components 14 and 16 are laid down in opposite directions, the twist in each of these yarn components will be neutralized in the final structure of the composite yarn. Similarly, sheath yarn components 14 and 16 are advantageously of about equal weight in order to provide further balance in the composite yarn.

The composite yarn 20 shown in FIG. 2 is similar to that of FIG. 1 except that core yarn component 22 constitutes a monofilament and internal and external sheath yarn components 24 and 26, respectively, each constitutes a monofilament. In all other structural and compositional respects, composite yarn 20 can be like that of composite yarn 10.

An alternative composite yarn 30 is illustrated in FIGS. 3 and 4. Composite yarn 30 comprises a core yarn component 33 and a braided sheath yarn component 34. As with core yarn components 12 and 22 of

ARM 24362

5,147,400

9

FIGS. 1 and 2, core yarn component 33 is made up of one or more biocompatible, essentially non-bioabsorbable and preferably elastic filaments 36 which define the longitudinal axis of composite yarn 30. Braided sheath yarn component 34 comprises individual sheath yarn filaments or sheath yarn filament bundles 35 which traverse core yarn component 33 in a substantially conventional braided configuration to provide core yarn component 33 with a braided tubular external sheath 34. The individual sheath yarn filaments or sheath yarn filament bundles 35 are biocompatible, bioabsorbable or semi-bioabsorbable, and relatively inelastic. In a preferred embodiment of the present invention as illustrated in FIGS. 3 and 4, sheath yarn component 34 comprises sheath yarn filaments of different chemical composition. For example, a portion of the sheath yarn filaments 35, e.g., 30 to 70% by weight, may be formed of a bioabsorbable polymer exhibiting relatively slow bioabsorption, e.g., polylactide or a copolymer comprising a high lactide mole percentage, while the remainder of the sheath yarn filaments 35 may be formed of a second bioabsorbable polymer which exhibits relatively fast bioabsorption, e.g., polyglycolide or a copolymer comprising a high glycolide mole percentage. Sheath yarn component 34 may also be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable.

In the embodiment illustrated in FIGS. 3 and 4, core yarn component 33 is preferably manufactured from Hytrel filaments 36 and has a denier of about 270, while sheath yarn component 34, which is braided on an eight carrier braider, has a denier of about 204, for a total denier of this composite yarn 30 of about 474.

FIG. 5 illustrates an anterior cruciate ligament prosthesis 37 manufactured from warp and filling composite yarns 10 of FIG. 1. Prosthesis 37 is constructed by constructing a sheath 31 about core 32 by weaving, braiding or knitting on a known or conventional loom. For example, the sheath may be braided about the core on a braiding machine which includes braider bobbins. Composite yarn forming the sheath may be wound onto an appropriate number of braider bobbins which are then loaded onto a carrier braider with the yarns on the bobbins then being braided and tied to form the sheath. The core (if one is required) can be pulled through the sheath, e.g. manually to form the prosthesis. In other words, the core will be at least partially surrounded by the sheath. Other prostheses illustrated herein can be manufactured in similar fashion. The sheath components of the individual composite yarns from which ligament prosthesis 30 is manufactured will erode over time due to their bioabsorption leaving only the nonabsorbable core component as a permanent or long term scaffold for new ligament tissue growth.

FIGS. 7-11 illustrate examples of other ligament prostheses which can be manufactured from the composite yarn of the present invention, e.g. as illustrated in FIGS. 1-3. More particularly, FIG. 7 illustrates a tubular ligament prosthesis or tendon augmentation device 40 having an unbraided center section 41 bounded by braided sections 42 and 43. The individual composite yarns 44 in the unbraided center section 41 can be drawn in generally parallel relationship, if required. The length of the unbraided center section 41 can vary, e.g., from about one or two inches up to about seven or eight inches. The unbraided center section 41 provides tensile strength and/or tissue ingrowth advantages.

10

Additionally, a tubular ligament prosthesis or tendon augmentation device 45 as illustrated in FIG. 8 can be manufactured from the composite yarn of the present invention. The prosthesis 45 is similar to the one illustrated in FIG. 7 and comprises an unbraided center section 46 bounded by braided sections 47 and 48. A helical wrap 100 is provided about the unbraided center section 46 to improve handling and manipulation of the unbraided section 46 during implantation, while absorption/degradation of the helical wrap 100 frees the individual yarns 49 of the center unbraided section 46 to provide the appropriate tensile strength and/or tissue ingrowth advantages. In this regard, the yarn forming the helical wrap 100 can be the composite yarn of FIGS. 1-3 or formed of a different kind of material, e.g. completely bioabsorbable or nonbioabsorbable material. The tubular ligament prostheses of FIGS. 7 and 8 are both constructed by braiding the end sections 42, 43 or 47, 48 in a known or conventional loom and, in the case of FIG. 8, additionally wrapping the helical yarn 100 about the center unbraided section 46, also with a known or conventional loom. The prostheses of FIGS. 7 and 8 are especially suitable as replacements for anterior cruciate ligaments.

FIG. 9 illustrates a braided prosthesis 70 which can be manufactured from the composite yarns of FIGS. 1-3 and which is also modified along the length thereof. More specifically, the prosthesis of FIG. 9 comprises a center region 50 bordered by first outer regions 51, 52, second outer regions 53, 54, third outer regions 55, 56, fourth outer regions 57, 58, and fifth outer regions 59, 60. The center region 50 comprises a sheath of braided composite yarn, e.g., as illustrated in FIGS. 1-3, about a core (not illustrated) also formed of composite yarn. First outer regions 51, 52 additionally comprise a wrapping 61 about the braided yarn, this wrapping 61 being formed of the same composite yarn as illustrated in FIGS. 1-3 or a different kind of material, e.g. a totally bioabsorbable or nonabsorbable material. This wrapping 61 serves to at least temporarily retain the sheath about the core.

The second outer regions 53, 54 also formed of tubular braided composite yarn as illustrated in FIGS. 1-3 with an appropriate core material (not illustrated) that forms a thicker core than any core present in center section 50 (the center section 50 can be coreless, if required). Third outer regions 55, 56 are divided as illustrated in FIG. 9 to form respective openings 62 and 63. This allows attachment means to be inserted through the respective openings to secure the ligament prosthesis 70 in place. As illustrated in FIG. 9, the sections 55, 56 around the openings 62 and 63 are also covered with wrapping 64 which is similar to the wrapping 61 covering regions 51 and 52.

Next, fourth outer regions 57 and 58 follow which are similar in structure and composition to second outer regions 53 and 54. Regions 57 and 58 narrow down into fifth outer regions 59 and 60 as illustrated in FIG. 9, which can be used, e.g. for threading the ligament prosthesis 70. All sections of prosthesis 70, including the various wrappings 61 and 64, can be fabricated together on a conventional known loom. Prosthesis 70 is especially suitable as a replacement for an anterior cruciate ligament.

FIG. 10 discloses a coreless prosthetic ligament 80 that can be prepared from the composite yarn illustrated in FIGS. 1-3. The coreless prosthetic ligament is braided with a wider central section 81, and a narrower

ARM 24363

5,147,400

11

outer section from which unwoven yarns 83 extend to form a leading section to enhance threading of prosthetic ligament 80 upon implantation. Sheath yarns 84 of prosthetic ligament 80 can be woven, braided, or knitted on a conventional loom. Sheath sections 81 and 82 of ligament prostheses 80 are tubular, i.e. coreless. Prostheses 80 is also especially suitable as a replacement for an anterior cruciate ligament.

As illustrated in FIG. 11, a ligament prosthesis 90 can be prepared from composite yarns illustrated in Figs. 1-3 of the present invention which form a sheath about a supporting structure (not illustrated). This supporting structure can be a core formed from the composite yarns as described above, or it can be a single, integral member, formed of semi-bioabsorbable or non-bioabsorbable material forming a supporting base for yarns 91. This supporting structure, along with the bundle of yarns 91, can be divided into two branches 90a and 90b, with the yarns 91 of the prosthesis retained on the supporting structure or core at various points by fastening means 92 which can also be constituted by composite yarn of FIGS. 1-3 or by other kinds of material, e.g. totally bioabsorbable or nonabsorbable filaments. In this regard, the yarns 91 need just be bundled together without any interweaving, braiding or knitting, so long as the yarns 91 are securely held together on the core by the fastening means 92. Alternatively, yarns 92 can be woven, knitted, or braided about the core on a conventional loom to form branches 90a and 90b.

Other prosthetic structures which can be prepared with the composite yarn of the present invention are apparent to one of skill in the art in light of the disclosure herein.

It is within the scope of this invention to coat or impregnate the prosthesis with, or otherwise apply thereto, one or more materials which enhance its functionality, e.g., surgically useful substances, such as those which accelerate or beneficially modify the healing process when the prosthesis is applied to a graft site. So, for example, the prosthesis can be provided with a therapeutic agent which will be deposited at the grafted site. The therapeutic agent can be chosen for its antimicrobial properties, capability for promoting tissue repair or for specific indications such as thrombosis. Thus, for example, antimicrobial agents such as broad spectrum antibiotics (gentamicin sulphate, erythromycin or derivatized glycopeptides) which are slowly released into the tissue can be incorporated into the prosthesis to aid in combating clinical and sub-clinical infections in a surgical or trauma wound site.

To promote wound repair and/or tissue growth, one or several growth promoting factors can be introduced into the tubular prosthesis, e.g., fibroblast growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor, magainin, and so forth. To decrease abrasion, increase lubricity, etc., the prosthesis can be coated with copolymers of glycolide and lactide and polyethylene oxide, calcium salts such as calcium stearate, compounds of the Pluronic class, copolymers of caprolactone, caprolactone with PEO, polyHEMA, etc. Especially advantageous is a coating of hyaluronic acid with or without cross-linking.

Additionally, polypeptides such as Human Growth Factor (HGF) can also be coated upon or impregnated in the prosthesis to promote healing. The term "Human Growth Factor" or "HGF" embraces those materials, known in the literature, which are referred to as such

12

and includes their biologically active, closely related derivatives. The HGFs can be derived from naturally occurring sources and are preferably produced by recombinant DNA techniques. Specifically, any of the HGFs which are mitogenically active and as such effective in stimulating, accelerating, potentiating or otherwise enhancing the wound healing process are useful herein, e.g., hEGF (urogastrone), TGF-beta, IGF, PDGF, FGF, etc. These and other useful HGFs and closely related HGF derivatives, methods by which they can be obtained and methods and compositions featuring the use of HGFs to enhance wound healing are variously disclosed, inter alia, in U.S. Pat. Nos. 3,883,497; 3,917,824; 3,948,875; 4,338,397; 4,418,691; 4,528,186; 4,621,052; 4,743,679 and 4,717,717; European Patent Applications 0 046 039; 0 128 733; 0 131 868; 0 136 490; 0 147 178; 0 150 572; 0 177 915 and 0 267 015; PCT International Applications WO 83/04030; WO 85/00369; WO 85/01284 and WO 86/02271 and UK Patent Applications GB 2 092 155 A; 2,162,851 A and GB 2 172 890 A, all of which are incorporated by reference herein. Of the known HGFs, hEGF, TGF-beta and IGF are preferred for use in the therapeutic composition of this invention.

The HGFs can be introduced with appropriate carrier such as carrier proteins disclosed, e.g., in "Carrier Protein-Based Delivery of Protein Pharmaceuticals", a paper of Biogrowth, Inc., Richmond, Calif., presented at a symposium held June 12-14, 1989 in Boston, Mass.

EXAMPLE 1

The following illustrates the manufacture of a ligament prosthesis as illustrated in FIG. 5.

A 420 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn as the core component and a lactide (80 mole percent)-glycolide (20 mole percent) copolymer yarn providing the sheath component.

Six plies of the 420 denier composite yarn were wound onto 32 braider bobbins. The bobbins were loaded onto a 32 carrier braider to provide braided sheath 31. About one meter of the yarns from the 32 bobbins was pulled manually in parallel to provide a core 32 of 80,640 (420×6×32) overall denier. Application of braided sheath 31 also 420×6×32 or 80,640 overall denier resulted in ligament prosthesis 37 possessing an overall denier of 161,280. The stress (force in Newtons)-strain characteristics of prosthesis 37 were measured and compared with the stress-strain characteristics of a human anterior cruciate ligament as reported in Noyes et al., *Journal of Bone and Joint Surgery*, Vol. 58-A, No. 8, p. 1074, et seq. (Dec. 1976). As shown in the plotted data of FIG. 6, the stress-strain characteristics of prosthesis 37 (continuous line) closely matched those of the natural tissue (broken line), an altogether remarkable achievement relative to known connective tissue prostheses.

EXAMPLE 2

The following illustrates manufacture of a tendon augmentation device 40 as illustrated in FIG. 7.

A 431 denier composite yarn as illustrated in FIG. 1 was formed from a Hytrel 7246 yarn to provide the core component 12, a lactide (80 mole percent)-glycolide (20 mole percent) copolymer yarn to provide the inner sheath component 14, and a lactide (10 mole percent)-glycolide (90 mole percent) copolymer yarn to provide the outer sheath component 16.

ARM 24364

5,147,400

13

Six plies of the 431 denier composite yarn were wound onto 16 braider bobbins. The bobbins were loaded onto a 16 carrier braider to provide braided sections 42 and 43. About 70 mm of the yarn from the 16 braider bobbins was braided to form one of sections 42 and 43, and then the braiding was stopped. Then, about 35 mm. of the yarn from the 16 braider bobbins was pulled manually to form the unbraided center section 41, and then braiding was continued for another 70 mm of the yarn to form the other of sections 42 and 43. The resulting tendon augmentation device 40 had a total denier of 41,376 ($431 \times 6 \times 16$).

The tendon augmentation device 40 was implanted in a canine knee replacing the center third of the patellar tendon. Physical testing was carried out comparing two tendon augmentation devices 40 (TAD-1 and TAD-2) to the center third of the canine patellar tendon (§ P.T.) being replaced. More specifically, the stress (force in Newtons) —strain or load-deformation characteristics of devices 40 and the canine patellar tendon were measured and compared with one another.

As shown in the plotted data of FIG. 12, the responses of both tendon augmentation devices 40 (TAD 1 and TAD 2) were very similar to the one third canine patellar tendon. Moreover, tendon augmentation devices 40 (TAD 1 and TAD 2) were generally stronger than the replaced canine patellar tendon which failed when too great a load was applied thereto.

EXAMPLE 3

A composite yarn as illustrated in FIGS. 3 and 4 was fabricated using Hytrel 7246 fibers as the core component 33 and bioabsorbable sheath component fibers 35 of two different chemical compositions: first bioabsorbable fibers 35' fabricated from an 80 mole percent lactide/20 mole percent glycolide copolymer, and second bioabsorbable fibers 35'' fabricated from a 10 mole percent lactide/90 mole percent glycolide copolymer. The first bioabsorbable fibers 35' were formed into yarn bundles, each yarn bundle comprising 12 filaments and having a total denier of 24. The second bioabsorbable fibers 35'' were also formed into yarn bundles, each yarn bundle comprising 17 filaments and having a total denier of 27.

The composite yarn was formed using three Hytrel yarn bundles, each Hytrel yarn bundle comprising 70 filaments, to form a core component 33 of approximately 270 denier. The braided sheath component 34 was formed around the Hytrel core component 33 using an 8 carrier braider, 4 carriers each of the first and second bioabsorbable yarn bundles. The composite yarn thus formed exhibited a tensile strength of 3.19 grams/denier, and is suitable for use in fabricating a connective tissue prosthesis of the present invention.

What is claimed is:

1. A connective tissue prosthesis comprising:
 - a) a core made up of a first biocompatible composite yarn extending in a lengthwise direction; and
 - b) a sheath surrounding the core, said sheath being fabricated from a second biocompatible yarn; the first composite yarn in said core (a) comprising a non-bioabsorbable core yarn component surrounded by an at least semi-bioabsorbable sheath yarn component.
2. The connective tissue prosthesis of claim 1, wherein the second biocompatible yarn in said sheath (b) comprises a non-bioabsorbable core yarn component

14

surrounded by an at least semi-bioabsorbable sheath yarn component.

3. The connective tissue prosthesis of claim 2 wherein the sheath yarn component is bioabsorbable.

4. The connective tissue prosthesis of claim 1 exhibiting stress-strain characteristics approximately those of the natural connective tissue replaced or augmented by the prosthesis.

5. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a ligament or tendon prosthesis.

6. The connective tissue prosthesis of claim 1 wherein said connective tissue prosthesis is a human anterior cruciate ligament prosthesis.

7. The connective tissue prosthesis of claim 1 in which the core component comprises at least one filament.

8. The connective tissue prosthesis of claim 7 in which the core (a) of the prosthesis comprises multiple composite yarns.

9. The connective tissue prosthesis of claim 7 wherein the core component comprises multiple filaments.

10. The connective tissue prosthesis of claim 1 in which the sheath component comprises at least one filament.

11. The connective tissue prosthesis of claim 10 wherein the sheath yarn component comprises multiple filaments.

12. The connective tissue prosthesis of claim 1 in which the core component is manufactured from at least one polymeric material selected from the group consisting of polyethylene homopolymers, polypropylene homopolymers, ethylene-propylene copolymers, ethylene propylene terpolymers, fluorinated hydrocarbons, fluorosilicones, isobutylenes, isoprenes, polyacrylates, polybutadienes, polyurethanes, and polyether-polyester copolymers.

13. The connective tissue prosthesis of claim 1 in which the core component possesses an elongation at break of at least about 30 percent.

14. The connective tissue prosthesis of claim 1 in which the sheath component is an absorbable, relatively inelastic polymeric material derived at least in part from a monomer selected from the group consisting of glycolic acid, glycolide, lactic acid, lactide, p-dioxanone, trimethylene carbonate, ε-caprolactone and hydroxyacetic acid.

15. The connective tissue prosthesis of claim 1 in which the sheath component is a lactide-glycolide copolymer.

16. The connective tissue prosthesis of claim 12 in which the sheath component is a lactide-glycolide copolymer containing from about 70 to about 90 mole percent lactide units.

17. The connective tissue prosthesis of claim 16 in which the sheath component is a lactide-glycolide copolymer containing from about 75 to about 85 mole percent lactide units.

18. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially woven.

19. The connective tissue prosthesis of claim 18 wherein the sheath (b) is entirely woven.

20. The connective tissue prosthesis of claim 1 further comprising at least one bioactive substance.

21. The connective tissue prosthesis of claim 1, wherein said sheath component is helically wound about said core component.

ARM 24365

5,147,400

15

22. The connective tissue prosthesis of claim 21, additionally comprising

a second sheath component helically wound about said sheath component in a different direction.

23. The connective tissue prosthesis of claim 22, in which said second sheath component is a lactide-glycolide copolymer.

24. The connective tissue prosthesis of claim 22, wherein said first and second sheath components have different ratios of absorption.

25. The connective tissue prosthesis of claim 1, wherein said sheath component is braided around said core component.

26. The connective tissue prosthesis of claim 25, wherein said sheath component comprises a plurality of bioabsorbable fibers, said fibers comprising at least two different chemical compositions.

27. The connective tissue prosthesis of claim 1, wherein said core (a) and sheath (b) together are branched at discrete locations to form gaps between branches of said prosthesis.

28. The connective tissue prosthesis of claim 27, wherein a yarn is wrapped about said sheath (b) at discrete locations to at least temporarily retain said sheath (b) about said core (a).

29. The connective tissue prosthesis of claim 28, wherein said wrapping yarn comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a at least semi-bioabsorbable sheath yarn component.

30. The connective tissue prosthesis of claim 29 wherein said sheath component of said wrapping yarn is bioabsorbable.

31. The connective tissue prosthesis of claim 1 wherein said sheath yarn component is bioabsorbable.

32. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially braided.

33. The connective tissue prosthesis of claim 32 wherein the sheath (b) is entirely braided.

34. The connective tissue prosthesis of claim 1 wherein the sheath (b) covering the core (a) is at least partially knitted.

35. The connective tissue prosthesis of claim 34 wherein the sheath (b) is entirely knitted.

36. A connective tissue prosthesis comprising:
a tubular component fabricated from composite yarn, said yarn comprising a biocompatible, core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

37. The connective tissue prosthesis of claim 36, comprising a center section where said yarn is unbraided and bordered by sections where said yarn is braided.

38. The connective tissue prosthesis of claim 37, additionally comprising

a helical wrap about said unbraided center section.

39. The connective tissue prosthesis of claim 38, wherein said helical wrap is fabricated from composite yarn comprising a biocompatible, non-bioabsorbable

16

core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

40. The connective tissue prosthesis of claim 39, wherein said sheath component is bioabsorbable.

41. The connective tissue prosthesis of claim 36, additionally comprising

a threading member attached to an end thereof, said threading member comprising a composite yarn which comprises a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-bioabsorbable sheath yarn component.

42. The connective tissue prosthesis of claim 41 wherein said sheath component is bioabsorbable.

43. The connective tissue prosthesis of claim 36 wherein said sheath component is bioabsorbable.

44. Method for manufacturing a connective tissue prosthesis, comprising

forming said connective tissue prosthesis from a first biocompatible composite yarn comprising a non-bioabsorbable core yarn component surrounded by an at least semibioabsorbable sheath yarn component.

45. The method of claim 44, wherein said connective tissue prosthesis comprises a core and a sheath, said core being at least partially surrounded by said sheath.

46. The method of claim 45, wherein said biocompatible composite yarn forms said core.

47. The method of claim 44, wherein said biocompatible composite yarn forms said sheath.

48. The method of claim 44, wherein the sheath is woven about the core.

49. The method of claim 48, wherein the sheath is braided from braider bobbins loaded onto a carrier braider, and the core is pulled through the thus-braided sheath.

50. The method of claim 48 wherein the sheath is braided about the core.

51. The method of claim 44 wherein said sheath component is bioabsorbable.

52. The method of claim 44 wherein the sheath is knitted about the core.

53. Method for manufacturing a tubular connective tissue prosthesis, comprising

forming a tubular component from composite yarn comprising a biocompatible, non-bioabsorbable core yarn component surrounded by a biocompatible, at least semi-absorbable sheath yarn component.

54. The method of claim 53 wherein the tubular component is formed by weaving.

55. The method of claim 53 wherein the tubular component is formed by braiding.

56. The method of claim 55, wherein the tubular component is braided from braider bobbins loaded onto a carrier braider.

57. The method of claim 53 wherein the tubular component is formed by knitting.

58. The method of claim 53 wherein the sheath component is bioabsorbable.

* * * * *

EXHIBIT 15

**CONOCO, INC. and CONOCO SPECIALTY PRODUCTS, INC.,
Plaintiffs-Appellees, v. ENERGY & ENVIRONMENTAL
INTERNATIONAL, L.C., Defendant-Appellant, and GERALD B.
EATON, RONALD N. GRABOIS and MICHAEL MONAHAN, De-
fendants.**

05-1363, -1461

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL
CIRCUIT**

2006 U.S. App. LEXIS 21036

August 17, 2006, Decided

PRIOR HISTORY: [*1] Appealed from: United States District Court for the Southern District of Texas. Judge John D. Rainey. *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 2006 U.S. Dist. LEXIS 25209 (S.D. Tex., Mar. 22, 2006)

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant company, found by the U.S. District Court for the Southern District of Texas to have literally infringed claim 1 of appellee patent holders' '937 patent, and to have infringed claims 1-3 of the '151 patent under doctrine of equivalents, challenged its claim construction for the '937 patent, its partial denial of summary judgment of non-infringement for the '151 patent, findings and conclusions of infringement, and injunction extension.

OVERVIEW: The patents in suit encompassed processes for making drag reducing agents (DRA) that were injected into oil and gas pipe-

lines to reduce friction inherent in pumping operations. The court stated that claim construction was a question of law reviewed de novo. Whether an accused device met all the limitations of those claims was a factual question reviewed for clear error. Infringement under the doctrine of equivalents was also a factual question reviewed for clear error. However, issues relating to the application of prosecution history estoppel were reviewed de novo. Regarding the '937 patent, the court rejected the alleged infringer's first contention that it did not literally infringe said patent because the district court erred in its claim construction and infringement analysis. With regard to the '151 patent, the company contended that the district court erred in its application of prosecution history estoppel to the patent holder's doctrine of equivalents claim. The court rejected the company's arguments for both amendment and argument-based estoppel. Finally, the district court's decision to extend the injunction to encompass polyethylene was not an abuse of discretion.

OUTCOME: The judgment was affirmed.

LexisNexis(R) Headnotes

Patent Law > Jurisdiction & Review > Standards of Review > General Overview

Patent Law > Jurisdiction & Review > Standards of Review > Clearly Erroneous Review

[HN1] On appeal from a bench trial, the U.S. Court of Appeals for the Federal Circuit reviews a district court's decision for errors of law and clearly erroneous findings of fact.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

Patent Law > Jurisdiction & Review > Standards of Review > Clearly Erroneous Review

Patent Law > Jurisdiction & Review > Standards of Review > De Novo Review

[HN2] Claim construction is a question of law that the U.S. Court of Appeals for the Federal Circuit reviews de novo. Whether an accused device meets all the limitations of those claims is a factual question reviewed for clear error.

Patent Law > Infringement Actions > Doctrine of Equivalents > General Overview

Patent Law > Jurisdiction & Review > Standards of Review > Clearly Erroneous Review

[HN3] Infringement under the doctrine of equivalents is a factual question reviewed by the U.S. Court of Appeals for the Federal Circuit for clear error.

Patent Law > Infringement Actions > Prosecution History Estoppel > General Overview

Patent Law > Jurisdiction & Review > Standards of Review > De Novo Review

[HN4] The U.S. Court of Appeals for the Federal Circuit reviews issues relating to the application of prosecution history estoppel de novo.

Patent Law > Jurisdiction & Review > Standards of Review > Abuse of Discretion

Patent Law > Remedies > Equitable Relief > Injunctions

[HN5] The U.S. Court of Appeals for the Federal Circuit reviews a district court's decision to extend injunctive relief for an abuse of discretion.

Civil Procedure > Sanctions > Contempt > General Overview

Patent Law > Jurisdiction & Review > Standards of Review > Clearly Erroneous Review

Patent Law > Remedies > Equitable Relief > Injunctions

[HN6] The U.S. Court of Appeals for the Federal Circuit reviews the factual findings during a contempt proceeding for clear error.

Patent Law > Claims & Specifications > General Overview

[HN7] Words of a claim are generally given the ordinary and customary meaning that they would have to a person of ordinary skill in the art at the time of the invention. However, this person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. Indeed, an inventor may use the specification to intentionally disclaim or disavow the broad scope of a claim. However, this intention must be clear, and cannot draw limitations into the claim from a preferred embodiment. Moreover, when a claim term is expressed in general descriptive words, the U.S. Court of Appeals for the Federal Circuit will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims.

Civil Procedure > Appeals > Reviewability > Preservation for Review

Patent Law > Infringement Actions > General Overview***Patent Law > Jurisdiction & Review > General Overview***

[HN8] Normally, a district court faced with a patent infringement suit engages in a two-step analysis, involving: (1) construing the disputed claims of the patent--a matter of law--and (2) comparing the accused device to the patent claims--a matter of fact. However, legal issues in patent infringement suits are not immune to the doctrine of waiver on appeal, and except for certain circumstances, those issues not raised below at the district court cannot be heard for the first time on appeal. Thus, a party may not introduce new claim construction arguments on appeal or alter the scope of the claim construction positions it took below. Moreover, litigants waive their right to present new claim construction disputes if they are raised for the first time after trial.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN9] A district court may engage in claim construction during various phases of litigation, not just in a Markman order. District courts may engage in rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves.

Patent Law > Infringement Actions > Claim Interpretation > General Overview***Patent Law > Jurisdiction & Review > Standards of Review > De Novo Review***

[HN10] When a district court explicitly construes a term sua sponte and applies that construction to the facts, the U.S. Court of Appeals for the Federal Circuit must review its construction de novo.

Patent Law > Claims & Specifications > Claim Language > Claim Transitions

[HN11] Transitional phrases, such as "comprising," "consisting of," and "consisting essentially of," are terms of art in patent law that define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The phrase "consisting of" signifies restriction and exclusion of unrecited steps or components. Although "consisting of" is a term of restriction, the restriction is not absolute. The Patent Board of Appeals has interpreted "consisting of" to close the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith. "Consisting of" does not exclude additional components or steps that are unrelated to the invention.

Patent Law > Claims & Specifications > Claim Language > Claim Transitions

[HN12] "Consisting of" is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. However, while "consisting of" limits the claimed invention, it does not limit aspects unrelated to the invention. It is thus necessary to determine what is limited by the "consisting of" phrase.

Patent Law > Claims & Specifications > Claim Language > Claim Transitions

[HN13] Impurities that a person of ordinary skill in the relevant art would ordinarily associate with a component on the "consisting of" list do not exclude the accused product or process from infringement.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN14] Impurities normally associated with the component of a claimed invention are implicitly

adopted by the ordinary meaning of the components themselves.

Patent Law > Infringement Actions > Claim Interpretation > Aids

[HN15] Claim construction involves the search for the ordinary and customary meaning of a claim term to a person of ordinary skill in the art. This meaning may be informed by the surrounding claim language, the specification, the prosecution history, and extrinsic evidence. Though not preferred over intrinsic evidence, extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or prior art has a particular meaning in the pertinent field.

Evidence > Testimony > Credibility > General Overview

Patent Law > Jurisdiction & Review > Standards of Review > General Overview

[HN16] As for the relative weight given to the testimony of both sides' expert witnesses, the U.S. Court of Appeals for the Federal Circuit accords the trial court broad discretion in determining credibility because the trial court saw the witnesses and heard their testimony.

Patent Law > Infringement Actions > Doctrine of Equivalents > General Overview

Patent Law > Infringement Actions > Prosecution History Estoppel > Abandonment & Amendment

Patent Law > Infringement Actions > Prosecution History Estoppel > Prosecution-Related Arguments & Remarks

[HN17] Under the doctrine of equivalents, a patentee may lay claim to those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes. However, prosecution history estoppel limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution. Prosecution history estoppel can occur during prosecution in one of two ways, either (1) by making a narrowing amendment to the claim (amendment-based estoppel) or (2) by surrendering claim scope through argument to the patent examiner (argument-based estoppel).

Evidence > Inferences & Presumptions > Rebuttal of Presumptions

Patent Law > Infringement Actions > Prosecution History Estoppel > Abandonment & Amendment

[HN18] When a patentee makes a narrowing amendment to a claim, the patent holder has the burden to demonstrate that the reason for the amendment was unrelated to patentability (e.g., to avoid prior art). When the record lacks explanation for the amendment, courts presume that the Patent and Trademark Office had a substantial reason related to patentability for including the limiting element added by amendment. Yet, this presumption is not an absolute bar, and the patent holder can rebut the presumption that the doctrine of equivalents will not apply. To do so, the patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent. A patentee may demonstrate this by showing (1) the equivalent may have been unforeseeable at the time of the application; (2) the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or (3) there may be some other reason suggesting that the patentee could not reasonably be

expected to have described the insubstantial substitute in question.

Patent Law > Infringement Actions > Prosecution History Estoppel > Prosecution-Related Arguments & Remarks

[HN19] To invoke argument-based estoppel, the prosecution history must evince a clear and unmistakable surrender of subject matter. Unlike amendment-based estoppel, courts do not presume a patentee's arguments to surrender an entire field of equivalents through simple arguments and explanations to the patent examiner. Though arguments to the examiner may have the same effect, they do not always evince the same clear disavowal of scope that a formal amendment to the claim would have. The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter.

Civil Procedure > Sanctions > Contempt > General Overview

Patent Law > Remedies > Equitable Relief > Injunctions

[HN20] Contempt proceedings are appropriate as long as the new issue does not raise a substantial question of infringement. If an accused infringer merely makes colorable changes to the accused product that infringed, a court may properly extend the injunction to the new device and find the party in contempt.

COUNSEL: Marcus E. Sernel, Kirkland & Ellis LLP, of Chicago, Illinois, argued for plaintiffs-appellees. With him on the brief were Jamie H. McDole, Kirkland & Ellis, and Lee L. Kaplan, Smyser Kaplan & Veselka, LLP, of Houston, Texas. Of counsel were Justin M. Waggoner, Kristen L. McKeever and Kristen E. Adler, Smyser Kaplan & Veselka, LLP.

Clarence E. Eriksen, Clarence E. Eriksen & Associates, of Houston, Texas, argued for de-

fendant-appellant. With him on the brief were Gordon G. Waggett, Gordon G. Waggett, P.C., and Michael J. Schaengold, Patton Boggs LLP, of Washington, DC.

JUDGES: Before BRYSON, Circuit Judge, ARCHER, Senior Circuit Judge, and GAJARSA, Circuit Judge.

OPINIONBY: GAJARSA

OPINION: GAJARSA, Circuit Judge.

Conoco, Inc. ("Conoco") brought suit against Energy & Environmental International, L.C. ("EEI"), Gerald Eaton, Ronald Grabois, and Michael Monahan for the alleged infringement of *U.S. Patent Nos. 5,244,937* ("the '937 patent") and *6,172,151* ("the '151 patent") (collectively "the patents in suit"). EEI stipulated that the patents in suit were valid and enforceable [*2] for purposes of the litigation. On April 1, 2004, the district court entered a Markman order construing the patent claims. *Conoco, Inc. v. Energy & Env'tl. Int'l, L.C.*, No. H-01-4242 (S.D. Tex. Apr. 1, 2004) ("Markman Order"). Thereafter, the court partially granted EEI's motion for summary judgment of non-infringement of the '*151 patent*' by holding that there was no genuine issue of material fact that EEI literally infringed the '*151 patent*', but that there was a sufficient issue of fact regarding Conoco's remaining claims for doctrine of equivalents infringement. *Conoco, Inc. v. Energy & Env'tl. Int'l, L.C.*, No. H-01-4242 (S.D. Tex. Apr. 27, 2004) ("Summary Judgment Order").

The district court held a bench trial and found inter alia that EEI literally infringed claim 1 of the '*937 patent*', that EEI infringed claims 1-3 of the '*151 patent*' under the doctrine of equivalents, and that defendants Eaton and Grabois did not have personal liability for the infringement. *n1 Conoco, Inc. v. Energy & Env'tl. Int'l, L.C.*, No. H-01-4242, slip op. at 59, 62 (S.D. Tex. Mar. 31, 2005) ("Findings of Fact

& Conclusions of Law"). The court further enjoined EEI from infringing [*3] the patent, id. at 68-69, and later extended its injunction to include the use of polyethylene wax ("PE wax"), *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, No. H-01-4242 (S.D. Tex. June 23, 2005) ("Contempt Order"). EEI now appeals the district court's claim construction for the '937 patent, its partial denial of summary judgment of non-infringement for the '151 patent, its factual findings and legal conclusions of infringement, and its extension of the injunction. As we discuss below, we agree with the district court and affirm.

N1 Conoco settled with Monahan prior to trial.

I. BACKGROUND

A. The Patents in Suit

The patents in suit encompass processes for making drag reducing agents ("DRA") that are injected into oil and gas pipelines to reduce friction inherent in pumping operations. By reducing friction, a supplier is able to pump more liquid more efficiently. The active ingredients in DRAs are high molecular weight polymers.

Developed in the 1970s, the first DRAs were gel-based with a jello-like consistency. These gel-based DRAs, however, were difficult to handle. Operators had difficulty storing and injecting the gel, and the gel-based [*4] DRAs had difficulty dissolving in the oil.

Eventually, a second, suspension-based DRA was developed with improved handling and dissolution characteristics. Suspension-based DRAs involve grinding a polymer at cryogenic temperatures and mixing them in a suspending material. One problem with suspension-based DRAs, however, is that the cryoground polymer may stick together or "agglomerate" after they are ground. To prevent

agglomeration, operators coat the polymer with a partitioning agent during grinding.

1. The '937 Patent

In general, the '937 patent teaches a process by which high-molecular-weight polyalphaolefin drag reducing polymer particles could be suspended in a water or water-alcohol liquid medium that was non-solvent with respect to the solid polymer particles. Conoco brought suit alleging infringement of claim 1, which reads:

1. A Process for the preparation of a stable nonagglomerating suspension of a solid oil soluble polyolefin friction reducing agent obtained from the polymerization of olefins containing from 2 to about 30 carbon atoms which comprises:

(1) subjecting said solid polyolefin friction reducing agent to grinding at cryogenic temperatures in the presence [*5] of an inert solid material to provide free flowing, finely divided polymer particles coated with said solid material, and

(2) combining the coated polymer particles with a water soluble polymeric thickening agent and a suspending material selected from the group consisting of water and water-alcohol mixtures, whereby a stable nonagglomerating suspension of the solid friction reducing agent is obtained.

'937 patent, col.7, l.66 -- col.8, l.13 (emphasis added).

2. The '151 Patent

According to Conoco, even though the '937 patent was widely accepted, it still had flaws. Some refiners were reluctant to inject a water-containing substance into certain products

like gasoline or diesel fuel. Furthermore, the commonly used metal stearate partitioning agent was not ideal for gasoline injection due to the metal emissions it caused during use and the formation of a thick paste that could not be injected when suspended in a pure-alcohol medium.

The invention disclosed in the '*151 patent* represents a process by which polymer particles could be suspended in alcohols and/or glycols using a fatty acid wax partitioning agent to provide a stable, nonagglomerating suspension. At trial, [*6] Conoco alleged that EEI infringed claims 1-3 of the '*151 patent*. Claim 1, a representative claim of the three, reads:

1. A method of reducing turbulent drag in a hydrocarbon liquid stream flowing through conduits, which comprises:

(a) forming a solid hydrocarbon soluble polyolefin friction reducing agent from olefins containing from 2 to 30 carbon atoms;

(b) finely dividing said soluble polyolefin friction reducing agent in the presence of a partitioning agent to provide a free flowing, polyalphaolefin material, said partitioning agent being a fatty acid wax;

(c) dispersing the free-flowing polyalphaolefin particles in a substantially nonaqueous suspending fluid medium selected from the group consisting of alcohols containing 14 or less carbon atoms, glycols and glycol-ethers; and

(d) adding said suspension to said hydrocarbon liquid stream in an amount of up to 100 ppm of said

reducing agent to reduce friction during turbulent flow through said conduits.

'151 patent, col.7, l.59 -- col.8, l.9 (emphasis added). The main contention in these claims is the use of the term "fatty acid wax." The specification notes that fatty acid waxes are "necessary" [*7] during the cryogrinding process. Col. 4, l. 17.

During prosecution, the applicants claimed from the beginning that the DRA was formed with a fatty acid wax partitioning agent such as stearamides. The examiner rejected the claims as obvious because, even though the prior art taught the use of talc, clay and metal stearates as partitioning agents, the prior Widiger patent taught the use of stearamides for preventing adhesion of films in the food packaging industry.

The applicants responded by pointing out that the Widiger patent was nonanalogous art. However, the examiner maintained the rejection, stating:

the definition of a fatty acid wax is an ester of long-chain fatty acids and long-chain alcohols, the applicants include stearamides in their definition of the fatty acid wax. It seems that the applicants is [sic] defining the fatty acid wax as the long-chain fatty acids and its derivatives; thus the metal stearates of Johnston seems to be functionally equivalent to stearamide.

Conoco subsequently cancelled its original claims and submitted 22 new claims that continued to claim the fatty acid wax limitation. Upon submission of the 22 new claims, one proposed claim, [*8] claim 21, did not contain

the fatty acid wax limitation. This element was later added by examiner amendment with no explanation.

After a meeting between the applicants and the examiner to explain the differences between metal stearate partitioning agents in a water or water/alcohol system and fatty acid waxes in a nonaqueous system, the examiner allowed the claims of the '*151 patent*, explaining that

Johnston et al. do not teach or reasonably suggest their coating agent to be a fatty acid wax such as stearamides and the like. Although Widiger et al. teach slip additives of amides such as stearamide for preventing the adhesion between surfaces of polyolefin articles, since applicant has shown the criticalities of using fatty acid wax as the partitioning agent over metal stearates (the salt forms of the fatty acid wax) in the video tape provided during the interview of August 4, 2000, thus, the instant claims are deemed novel.

(emphasis in original).

B. Claim Construction

Before trial, the parties asked the court to explicitly construe "water-alcohol mixture" in the '*937 patent* and "fatty acid wax" in the '*151 patent*. The court construed "water-alcohol [*9] mixture" to be "a suspending material containing more than negligible amounts of water and alcohol." Markman Order at 8. The court rejected EEI's proposed construction that incorporated language from the specification noting a water-alcohol mixture that contained 30% water. Furthermore, the court read the specification to require more than negligible amounts of water because the specification required an "aqueous"

suspending material that it defined as a "medium 'made from, with or by means of water.'" Id. at 7 (citing Webster's New International Dictionary 135 (2d ed. 1934)).

The court construed "fatty acid wax" to be "stearamides and similar amide derivatives." Id. at 12. The court recognized that the applicants accepted the examiner's more limited definition of "fatty acid wax" during prosecution that excluded the derivatives of fatty acids such as metal stearates.

C. Alleged Infringing Activity

EEI began producing DRAs in 1996 with a gel-based product. In late 1999, EEI developed and began selling a suspension-based DRA called XPAND High Internal Product Ratio ("HIPR"). The Original Process for making HIPR used Alfol-2 as a suspending medium, and the district [*10] court found that HIPR contained the following materials: (1) Alfol-2 -- 67 percent; (2) Carbopol -- 0.7 percent; (3) PE Wax -- 0.8 percent; (4) C30+ Wax -- 8.7 percent; (5) Polymer -- 23 percent; and (6) Acid -- 0.5 percent.

The district court found that Alfol-2, the accused "suspending material," contained 8 to 15 percent water and 80 to 82.31 percent ethanol. The remaining ingredients consist primarily of a denaturing agent known as methyl isobutyl ketone ("MIBK"), which is added to industrial alcohols to avoid paying liquor taxes and to avoid human consumption. EEI presented evidence that Alfol-2 consisted of the following materials: (1) Water -- 8 percent; (2) Ammonia -- 0.08 percent; (3) Ethanol -- 82.31 percent; (4) Other Hydrocarbons -- 0.38 percent; (5) Isopropanol -- 2.35 percent; (6) Methanol -- 0.09 percent; (7) Butanol -- 0.94 percent; (8) MIBK -- 4.7 percent; (9) Heptane -- 1.12 percent. The district court found that any non-alcohol and non-water components in Alfol-2, such as the ammonia, heptane and MIBK, were impurities.

In April of 2001, EEI switched from its Original Process that used Alfol-2 to its Current Process that used Alfol-6. Alfol-6 was composed of substantially-pure [*11] hexanol as a suspending medium; therefore, the Current Process did not infringe the '937 *patent* because the suspending medium was not composed of a water-alcohol mixture. However, Conoco claimed the Current Process infringed the '151 *patent*.

At trial, EEI conceded that the Current Process met every element of claims 1-3 of the '151 *patent* except for the requirement that the partitioning agent be a "fatty acid wax." EEI's Current Process uses C30+ wax as the partitioning agent. C30+ wax is not a "fatty acid wax" or stearamide as defined by the patent. It is a straight hydrocarbon wax.

D. District Court Orders

1. Summary Judgment

Before trial, EEI moved for summary judgment of non-infringement on the '151 patent claims. It argued that Conoco was estopped from alleging doctrine-of-equivalents infringement because the inventors argued during prosecution that "fatty acid wax" applied to stearamides and the like, therefore excluding all other equivalent compounds. The district court denied the motion and stated that Conoco was not estopped because the fatty acid wax limitation was present throughout prosecution, the limitation was not amended for reasons related to patentability, [*12] and during prosecution Conoco only surrendered application of the limitation to metal stearates, not hydrocarbon waxes. Furthermore, even if there had been a narrowing of the claims, the district court held that Conoco could rebut any estoppel presumption because the evidence indicated that the use of C30+ wax was unforeseeable and only tangentially related to the metal stearate disclaimer.

2. Findings of Fact and Conclusions of Law

After conducting a bench trial, the district court issued its findings of fact and conclusions of law. In regards to the '937 *patent*, the court found that EEI's HIPR product was a stable nonagglomerating suspension when it entered the pipeline based on EEI memos and expert testimony. Further, EEI's Original Process contained a meaningful amount of water in its suspending medium that made it a "water-alcohol mixture" for purposes of the claims. The court found that any water-alcohol mixture over 1 to 2 percent water was not negligible in this context because it would "impact[] the density and suspension capabilities of the suspending medium." Findings of Fact and Conclusions of Law at 18. Last, the court found that all other non-water and non-alcohol [*13] components, such as MIBK, were impurities that were not to be counted against the exclusive "consisting of" language. Thus, EEI's Original Process for manufacturing HIPR literally infringed the '937 *patent*.

Next, the district court found that the C30+ wax was equivalent to the "fatty acid wax" limitation in the '151 *patent* under the function-way-result test. The C30+ wax served the same function by preventing agglomeration of the polymer in a nonaqueous suspension. The C30+ wax performed this function in substantially the same way by coating the polymer during the cryogrinding process. The C30+ wax achieved the same result by creating a free-flowing polymer suspended in a nonaqueous solution.

3. Contempt Hearing

In the district court's final judgment, it enjoined EEI to "cease all manufacturing, offers for sale, and sales of its infringing HIPR slurry drag reducing agent product effective immediately." EEI, however, continued to manufacture its HIPR product and substituted PE wax for the C30+ wax. Conoco moved to find EEI in contempt of the injunction. The court denied the motion because its order was unclear and could be read to allow the use of PE wax. The district

court clarified [*14] its order and extended the injunction to include EEI's reformulated process using PE wax.

EEI filed a timely appeal in this court, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

[HN1] "On appeal from a bench trial, we review a district court's decision for errors of law and clearly erroneous findings of fact." *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1123 (Fed. Cir. 2000). [HN2] Claim construction is a question of law that we review de novo. See *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Whether an accused device meets all the limitations of those claims is a factual question we review for clear error. See *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 906 (Fed. Cir. 2005).

[HN3] Infringement under the doctrine of equivalents is also a factual question that we review for clear error. See *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1300 (Fed. Cir. 2001). However, [HN4] we review issues relating to the application of prosecution history estoppel de novo. [*15] See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1368 (Fed. Cir. 2003) (en banc).

[HN5] We review a district court's decision to extend injunctive relief for an abuse of discretion. See *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 404 (Fed. Cir. 1989). [HN6] We review the factual findings during a contempt proceeding for clear error. *Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 154 F.3d 1345, 1351 (Fed. Cir. 1998).

B. The '937 Patent

First, EEI contends that it did not literally infringe the '937 patent because the district

court erred in its claim construction and infringement analysis. As part of its recitation of error, EEI claims that the district court erred by construing "water-alcohol mixture" to mean more than negligible amounts of water, by finding Alfol-2 was a suspending medium "consisting of" a water-alcohol mixture, and by finding the accused product to be stable and nonagglomerating.

1. "Water-Alcohol Mixture"

First, EEI asserts that the district court misconstrued the term "water-alcohol mixture" because it did not limit the term composition to at least 30 percent water [*16] as described in the specification. In *Phillips v. AWH Corp.*, we reaffirmed our often stated rule that the [HN7] "words of a claim 'are generally given [the] ordinary and customary meaning'" that they would have to a person of ordinary skill in the art at the time of the invention. 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). However, this "person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313; see also *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996) (holding that the claims "must be read in view of the specification, of which they are a part"). Indeed, an inventor may use the specification to intentionally disclaim or disavow the broad scope of a claim. *Phillips*, 415 F.3d at 1316.

However, this intention must be clear, see *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002) [*17] ("The patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope."), and cannot draw limitations into the claim from

a preferred embodiment, see *Phillips*, 415 F.3d at 1323 ("[W]e have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). Moreover, "when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998); *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed. Cir. 1996).

Here, the specification states that the "amount of alcohol employed in the suspending material may vary widely but it usually forms between about 0 and 70 weight percent of the suspending material, and more usually between about 30 and about 50 weight [*18] percent." '937 patent, col.5, ll.19-23 (emphasis added). EEI maintains that this language explicitly limits the amount of alcohol in the suspending medium to a numerical range--between 0 and 70 percent. However, this language refers to a preferred embodiment of the invention, and the given numerical ranges are not used in a context meant to limit the claims. In fact, the language itself inherently recognizes that the numerical range should not limit the claim by noting that the amount of alcohol "may vary widely" and "usually" falls within a numerical range. Thus, the patentee did not limit the claim term as EEI suggests, n2 and the district court did not err in its claim construction.

n2 EEI further contends that the district court's construction reads the "water" limitation out of the claim because it only requires a non-negligible amount of water. EEI's additional argument stems from the description of the invention as "inexpensive and environmentally safe." It maintains that for the product to be inexpensive and environmentally safe it needs to contain a substantial amount of water. We,

however, find even less support for EEI's proposed construction because this language only serves to describe the benefits of having an aqueous suspending material and not a specific range of water in that material.

[*19]

2. "Consisting of" and "Stable Nonagglomerating Suspension" Claim Terms

Next, EEI argues that the district court erred by misconstruing the terms "consisting of" and "stable nonagglomerating suspension." EEI suggests that the court has erred in its claim construction and that we should review the construction of both terms de novo. Conversely, Conoco argues that EEI waived its right to ask for explicit claim construction on both terms because it conceded they were not in dispute by not raising the issue before, during, or after trial. n3

n3 Conoco contends that EEI failed to raise these issues at any time below, however, there was at least sufficient argument post trial to address the issue on appeal. Here, we address any failure to argue claim construction either before or during trial.

[HN8] Normally, a district court faced with a patent infringement suit engages in a two-step analysis, involving: (1) construing the disputed claims of the patent--a matter of law--and (2) comparing the accused device to the patent claims--a matter of fact. *Cybor Corp.*, 138 F.3d at 1454, 1456. However, legal issues in patent infringement suits are not immune to [*20] the doctrine of waiver on appeal, and except for certain circumstances, those issues not raised below at the district court cannot be heard for the first time on appeal. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1344-45 (Fed. Cir. 2001). Thus, a party may not

introduce new claim construction arguments on appeal or alter the scope of the claim construction positions it took below. *Id.* at 1346-47; see also *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1296 (Fed. Cir. 2005). Moreover, litigants waive their right to present new claim construction disputes if they are raised for the first time after trial. See *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1360 (Fed. Cir. 2004).

In *Eli Lilly*, the appellant argued that the district court erred by not construing a claim before sending the underlying inventorship issue to the jury. *Id.* However, we held that because the appellant waited to raise the argument until after the presentation of all the evidence to the jury, it waived the right to seek a construction of the newly disputed terms. *Id.* As a result, the appellant "implicitly [*21] conceded that the meanings of the terms in [the claim] are clear and not in need of construction." *Id.*

On the other hand, [HN9] a district court may engage in claim construction during various phases of litigation, not just in a Markman order. We have recognized that district courts may engage in "rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." *Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) (citing *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996)).

In the present case, EEI suggests that we review the terms "consisting of" and "stable nonagglomerating suspension" de novo. Because "consisting of" is a term of art in patent law with its own construction, MPEP § 2111.03 (8th ed., Rev. 1, Feb. 2003); see also *Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1382 (Fed. Cir. 2000), we will apply that legal construction, discussed below, and review the court's infringement analysis for clear error. n4 The second term, "stable nonagglomerating [*22] suspension," is not such a term of art. As

Conoco suggests, EEI waived its right to have that term construed and therefore conceded that the construction was clear and not in need of construction. However, the district court explicitly construed the term in its Findings of Fact and Conclusions of Law stating,

53. The Court reads the term "stable nonagglomerating suspension" to mean that the polymer particles are stable and not agglomerating at the time that the DRA is introduced into the pipeline

54. Under the '937 patent, a product is stable when the polymer particles are suspended in water or a mixture of water and alcohol with the addition of a water soluble thickening agent, if needed Other things being equal the nearer the density of the suspending medium is to the density of the polymer, the easier it is to form the stable suspension of the invention.

[HN10] Because the court explicitly construed the term sua sponte and applied that construction to the facts, we must review its construction de novo. See *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1343-45 (Fed. Cir. 2002) (reviewing a court's claim construction [*23] within its findings of fact and conclusions of law after a bench trial de novo).

n4 Though it is not inconceivable that a patentee could break with conventional claim construction and become his own lexicographer, see *Phillips*, 415 F.3d at 1316, we find no instances where EEI asked for a contrary claim construction nor any instance where the court specially construed the term sua sponte. Thus, any

argument that "consisting of" take on a special meaning is waived.

a. "Consisting of"

First, EEI alleges that the patentee's use of "consisting of" limits the scope of the '937 patent to exclude products performing only the recited steps of the patent "and nothing else." EEI contends that the district court erred by allowing the accused process's suspension medium to include MIBK, a non-alcohol, in spite of the limitation that the suspending medium consist of water or a water-alcohol mixture.

[HN11] Transitional phrases, such as "comprising," "consisting of," and "consisting essentially of," are terms of art in patent law that "define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope [*24] of the claim." MPEP § 2111.03; accord *Vehicular Techs. Corp.*, 212 F.3d at 1382-83. The phrase "consisting of" signifies restriction and exclusion of unrecited steps or components. MPEP § 2111.03. Although "consisting of" is a term of restriction, the restriction is not absolute. The Patent Board of Appeals has interpreted "consisting of" to "close[] the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (Pat. Office Bd. App. 1948); see also *Bethell v. Koch*, 57 C.C.P.A. 1233, 427 F.2d 1372, 1373-74 (C.C.P.A. 1970) (noting the parties' concession of a similar meaning of "consisting of").

We have explained that "consisting of" does not exclude additional components or steps that are unrelated to the invention. See *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331-32 (Fed. Cir. 2004). In *Norian Corp.*, the District Court for the Northern District of California found as a matter of law that a product containing an unrecited element did not infringe *U.S. Patent No. 6,002,065* ("the '065 patent") because the transitional [*25] phrase "consisting of" excluded

the additional element from the protection of the patent. *Id. at 1331*. Specifically, the '065 patent taught a kit containing specified chemicals; the infringing kit contained all the recited elements of the '065 patent, but added one element unrelated to the invention disclosed in the '065 patent--a spatula. *Id.* The district court held that adding the spatula to an otherwise infringing product avoided infringement of the '065 patent.

On appeal, we reversed the district court's holding and explained,

[HN12] "Consisting of" is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. However, while "consisting of" limits the claimed invention, it does not limit aspects unrelated to the invention. It is thus necessary to determine what is limited by the "consisting of" phrase.

Id. at 1331-32 (citation omitted). We held that the invention disclosed in the '065 patent was directed to a kit containing specified chemicals, and although the claims explicitly recited that no other chemical could be included in the composition, a competitor could not avoid [*26] infringement by adding a component unrelated to the invention. *Id.*

Similarly, [HN13] impurities that a person of ordinary skill in the relevant art would ordinarily associate with a component on the "consisting of" list do not exclude the accused product or process from infringement. EEI contends that MIBK is not an impurity because it was purposely added to the alcohol to denature it. However, the intentional addition of a component does not change its status as an "impurity ordinarily associated therewith." See *Davis*, 80 U.S.P.Q. at 450.

MIBK is a common impurity in industrial alcohols in order to prevent a liquor tax from being applied. If, however, MIBK had been added to adjust the stability of the suspending medium or prevent agglomeration of polymer, it may not have been an impurity and therefore EEI would most likely not infringe. Thus, [HN14] impurities normally associated with the component of a claimed invention are implicitly adopted by the ordinary meaning of the components themselves. n5 See *Phillips*, 415 F.3d 1303 at 1312-13 ("The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in [*27] the art . . .").

n5 We are not presented with the question of whether impurities not normally associated with a component would exclude the accused process from infringement; however, as in *Norian Corp.*, the additional component must be related to the invention. 363 F.3d at 1331-32.

The district court found as a matter of fact that Alfol-2 consisted of water and alcohol and that any non-alcohol and non-water components, such as MIBK, were impurities. This conclusion was based on the testimony of EEI's expert, who acknowledged that the small amounts of ammonia and heptane in the suspension were impurities and was impeached by prior testimony indicating MIBK was also an impurity. The court's findings were based on the testimony of persons of ordinary skill in the art who testified that MIBK has little to no effect on the present invention and is normally associated with industrial alcohols to reduce tax liability. Accordingly, there was substantial evidence to support the district court's findings that the MIBK and the other non-alcohol/non-water components were impurities, and the district court did not clearly err by finding that Alfol-2 met [*28] the claim limitations of the suspending medium.

b. "Stable Nonagglomerating Suspension"

Next, EEI argues that the district court misconstrued the claim term "stable nonagglomerating suspension." After consideration of the court's Findings of Fact and Conclusions of Law and the parties' arguments, the primary contention centers on the the word "stable." n6 Though the court does not give a short concise construction of the term as it did for other terms in its Markman order, we may paraphrase the court's construction from its findings as follows: a suspension is stable under the '937 *patent* when the density of the polymer closely matches the density of the suspending material and thickening agent. The suspension may separate over time, but when the suspension is injected into the pipeline it is stable.

n6 The parties do not contest the meaning of "nonagglomerating," which requires that the ground polymer particles remain separate individual particles.

EEI maintains that the court improperly construed the term to mean stable "at the time the DRA is introduced into the pipeline." Appellant's Br. at 42. Alternatively, EEI argues that the proper construction requires [*29] a suspension capable of being "shipped over large distances while retaining [its] properties." Id. at 43. EEI's argument stems from a section of the specification stating:

The suspensions obtained by the described procedures are homogeneous dispersions, stable and nonagglomerating, and may be shipped over large distances while retaining these properties.

'937 *patent*, col.4, ll.46-49. We agree in part with EEI's argument, but we do not find error in

the district court's reasoning. Rather, the court's apparent construction can be read congruently with EEI's proposed construction. In other words, a stable suspension at the time of pipeline injection will be stable enough to retain its properties over a long period of time, e.g., a period long enough to ship the product over large distances. As the court's construction implicitly recognizes, there is no limitation in the claim that requires the patented DRA to be transported over large distances or sit for long periods of time before it is introduced to a pipeline.

[HN15] Claim construction involves the search for the ordinary and customary meaning of a claim term to a person of ordinary skill in the art. *Phillips*, 415 F.3d 1303 at 1312. [*30] This meaning may be informed by the surrounding claim language, the specification, the prosecution history, and extrinsic evidence. *Id.* at 1314-19. Though not preferred over intrinsic evidence, *id.* at 1317,

extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology . . . , to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or prior art has a particular meaning in the pertinent field.

Id. at 1318. In this case, the claim language itself suggests that a person practicing the patent will create a stable suspension from a mixture of the polymer, suspending material, and thickening agent. '937 patent, col.8, ll.8-13. Further, the specification elaborates that "[o]ther things being equal the nearer the density of suspending

medium is to the density of the polymer the easier it is to form the stable suspension of the invention." Col.5, ll.12-14. The specification [*31] describes an embodiment of the process to include adding thickening agent--thereby increasing density of the suspending medium--"until a stable suspension is obtained." Col. 4, ll. 34-35. These statements suggest that stability is inversely proportional to the density difference between the suspending liquid and the solid polymer particles. In other words, as the difference between the density of the polymer particles and the suspending liquid decreases (i.e., their densities reach the same or similar value), the stability of the suspension increases.

However, the experts agreed that any suspension will eventually separate given enough time. As Conoco's expert witness, Joel Barlow, noted in his direct testimony,

And as we discussed . . . stable has a time frame associated with it, . . . you can look at a mountain and say it's stable, but it's not stable geologically. So, it's a time frame issue.

And here I think everybody in the business says stable has to mean that the material stays suspended long enough to be useful in delivery and pumping into the pipelines.

Therefore, considering both the intrinsic and extrinsic evidence for the ordinary meaning of "stable [*32] nonagglomerating suspension," the district court's construction was not in error. The court's construction requiring that the suspension be stable at the time it is introduced was merely a recognition that the process could be completed at the time of pipeline introduction and did not have to be shipped over long distances. The court's construction of the term "stable" is correct.

Likewise, the court did not err in its application of the facts to that construction. EEI contends that it presented evidence that the accused product was not stable and that the polymer quickly settled out. However, Conoco presented contrary evidence comprising (1) EEI's representations to customers that its product was stable and nonagglomerating, (2) EEI's representations of stability to the PTO, and (3) EEI's concession that the product is stable when injected into the pipeline. Moreover, the district court determined that Conoco's witnesses were more credible than EEI's. See *Energy Capital Corp. v. United States*, 302 F.3d 1314, 1329 (Fed. Cir. 2002) [HN16] ("As for the relative weight given to the testimony of both sides' expert witnesses, we accord the trial court broad discretion in determining [*33] credibility because the court saw the witnesses and heard their testimony."). Thus, there is sufficient evidence to support the district court's finding.

C. The '151 Patent

EEI further contends that the district court erred in its application of prosecution history estoppel to Conoco's doctrine of equivalents claim under the '151 patent. EEI asserts that Conoco was precluded from claiming a "fatty acid wax" equivalent because of an amendment and arguments made during prosecution. This argument is based on two events that occurred during prosecution. First, an examiner's amendment during prosecution added the "fatty acid wax" term to one of the patent claims without explanation. Second, during prosecution the applicant argued that metal stearates were not covered by the "fatty acid wax" limitation. EEI maintains that either of these events acts to estop Conoco from asserting that C30+ wax is an equivalent of a fatty acid wax.

[HN17] Under the doctrine of equivalents, Conoco may lay claim to "those insubstantial alterations that were not captured in drafting the original patent claim but which could be created

through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002). [*34] However, prosecution history estoppel limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution. *Id.* at 733-34. We have recognized that prosecution history estoppel can occur during prosecution in one of two ways, either (1) by making a narrowing amendment to the claim ("amendment-based estoppel") or (2) by surrendering claim scope through argument to the patent examiner ("argument-based estoppel"). *Deering Precision Instruments, LLC v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1324 (Fed. Cir. 2003). EEI argues that both occurred here.

1. Amendment-based Estoppel

First, EEI argues that the examiner's amendment that added "fatty acid wax" to one of 22 new claims estopped Conoco's equivalents argument. [HN18] When a patentee makes a narrowing amendment to a claim, the patent holder has the burden to demonstrate that the reason for the amendment was unrelated to patentability (e.g., to avoid prior art). *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997). When the record lacks explanation [*35] for the amendment, we "presume that the PTO had a substantial reason related to patentability for including the limiting element added by amendment." *Id.*; accord *Festo*, 535 U.S. at 735, 739.

Yet, this presumption is not an absolute bar, and the patent holder can rebut the presumption that the doctrine of equivalents will not apply. To do so, "the patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo*, 535 U.S. at 741. A patentee may demonstrate this by showing "[(1)] [t]he equivalent may have been

unforeseeable at the time of the application; [(2)] the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or [(3)] there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 740-41.

Here, there was an examiner's amendment to add the fatty acid wax limitation to one of the claims. Conoco maintains that the amendment was not [*36] related to patentability, but instead added merely to correct an obvious omission. We agree and therefore find no error in the district court's finding.

Each of the 16 original claims of the '151 patent application limited the partitioning agent to a fatty acid wax directly or through relation to an independent claim. Throughout the prosecution history, the examiner and applicants focused their attention on the meaning of the "fatty acid wax" limitation as compared to metal stearate partitioning agents.

Moreover, once the applicants cancelled the original claims and submitted 22 new claims, all but the first claim lacked the fatty acid wax limitation--presumably making the new claims broader than originally argued. Nevertheless, the examiner and applicants continued to focus their arguments as if the limitation was present, arguing the difference between fatty acid waxes and metal stearates. Such evidence indicates that the amendment was the correction of an inadvertent omission rather than the intentional narrowing of a broad claim for patentability purposes. Thus, the district court did not err by finding that the claim was not amended for purposes of patentability.

2. Argument-based [*37] Estoppel

Next, EEI contends that Conoco is also estopped by the repeated arguments the patentees made to explain the term "fatty acid wax" during prosecution. EEI maintains that the patentees cannot claim an equivalent because it specifi-

cally limited the term by arguing that fatty acid wax referred to stearamides and did not include metal stearates. [HN19] To invoke argument-based estoppel, however, "the prosecution history must evince a clear and unmistakable surrender of subject matter." *Deering Precision*, 347 F.3d at 1326 (citation and punctuation omitted). Unlike amendment-based estoppel, we do not presume a patentee's arguments to surrender an entire field of equivalents through simple arguments and explanations to the patent examiner. Though arguments to the examiner may have the same effect, they do not always evidence the same clear disavowal of scope that a formal amendment to the claim would have. Compare *Festo*, 535 U.S. at 739 (requiring courts "to presume that the patentee surrendered all subject matter between the broader and the narrower language" when an amendment is made for purposes of patentability) with *Deering Precision*, 347 F.3d at 1326 [*38] (requiring the prosecution history to "evince a clear and unmistakable surrender of subject matter" before estopping an equivalents argument). "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Cybor*, 138 F.3d at 1457.

Here, for instance, there is clear surrender of metal stearates, but there has not been a clear surrender of other possible equivalents. As the examiner noted, "applicant [showed] the criticalities of using fatty acid wax as the partitioning agent over metal stearates" in a video presented to the examiner. In reference to stearamides, the patentees merely explained what a fatty acid wax was and how it operated in the invention. The prosecution history arguments here merely demonstrate to the examiner that a fatty acid wax was not the same as a metal stearate to alleviate the examiner's obviousness concerns. Though this may be enough to clearly disavow metal stearates as equivalents of fatty acid waxes, it is not a clear surrender of all fatty acid wax equivalents.

D. The Contempt Hearing and Expansion of the Injunction

Lastly, EEI argues that [*39] the district court should have considered evidence and conducted further evidentiary hearings to determine whether PE wax was the equivalent of "fatty acid wax" and was therefore infringing. [HN20] "Contempt proceedings are appropriate as long as the new issue does not raise a substantial question of infringement." *Additive Controls & Measurement Sys. v. Flowdata, Inc.*, 154 F.3d 1345, 1350 (Fed. Cir. 1998). If an accused infringer merely makes colorable changes to the accused product that infringed, a court may properly extend the injunction to the new device and find the party in contempt. See *id.* at 1350-51. Here, the court heard testimony

that PE wax was the same as C30+ wax and that they functioned similarly in this context. Thus, the court's decision to extend the injunction to encompass PE wax was not an abuse of discretion.

III. CONCLUSION

In this appeal, EEI asks us to review the district court's final judgment that found EEI liable for infringement of Conoco's '937 and '151 patents. For the reasons stated in this opinion, we find no reversible error. Accordingly, we affirm.

AFFIRMED

Costs to Appellee.

EXHIBIT 16

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

**Declaration of Dr. David Brookstein In Support of DePuy Mitek's
Claim Interpretation of the Hunter Patent and Summary Judgment of Infringement**

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.
2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.
3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.
4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and conducted research in

the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems.

B. Work Experience

5. From 1980 to 1994, I worked at Albany International Research Co. At Albany International Research, I was an Associate Director from 1992 to 1994. From 1983 to 1992, I was an Assistant Director. From 1980 to 1982, I was a Senior Research Associate. While at Albany International Research Co., I directed all activities of the professional engineering group and was responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. My accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous performs for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures.

C. Education

6. I have a Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.

7. I have a Master of Science in Textile Technology from M.I.T., 1973.

8. I also hold a Bachelor of Textile Engineering, from Georgia Tech, 1971.

9. I also attended the Harvard Business School Summer Program on Research Management in 1990 and the Harvard Graduate School of Education MLE Summer Program, 1998.

10. When I was a researcher at Albany International Research Co., in the late 1980's, I led a program that involved the development of braided sutures for a commercial client. While at Albany, I researched, developed, tested and evaluated numerous braided and woven biomedical implants, including woven ACL prosthesis, braided artificial arteries, and textile-based,

resorbable bone plates and screws. Furthermore, I have taught textile engineers at the undergraduate and graduate level at Philadelphia University materials that involve the design, construction, braiding, manufacturing, and processing of textile structures that includes braids. Specifically, among other things, I have taught courses in Fiber Science which include fiber and yarn tensile, bending, and compression properties. Additionally, I was awarded the TechTextil Innovation Prize (Germany) in 1993 for my work in braiding.

11. My publications and patents for which I am an inventor are listed in my curriculum vitae (Ex. 1).

12. I have been asked to prepare this declaration based on my prior reports, deposition testimony, and Arthrex's motion for summary judgment. This declaration is basically my prior opinions reformatted to address the issues that I have been asked to address.¹

II. Legal Framework of My Opinions

13. I understand that the statutory basis for a determination of direct patent infringement is set forth in 35 U.S.C. §271(a) which states:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any Patented invention, within the United States or imports into the United States any Patented invention during the term of the Patent therefore, infringes the Patent.

14. I understand that an analysis of direct infringement requires two steps. First, the Court determines the meaning of the claims. Then, the properly construed claims are applied to a product to determine whether it infringes the Patent. I understand there are two types of direct infringement -- literal infringement and infringement under the doctrine of equivalents.

15. Infringement is "literal" when each claim limitation is literally present in a device.

I understand that even if a device does not literally have each claim limitation, there is still

¹ For purposes of this declaration, I use the term FiberWire to refer to Arthrex's FiberWire and TigerWire's products except where noted.

infringement if the device has an equivalent of the claimed limitation that is not literally present.

I understand that one method for determining whether a structure is equivalent to a claim limitation is the insubstantial differences test. Under this test, if the differences between the structure and the claim element are insubstantial, then they are equivalent. One method for determining whether the differences are insubstantial is whether the structure in the accused device “performs substantially the same function in substantially the same way to obtain the same result” (“function/way/result test”) as the claimed element.

III. If “General Purpose PE” Is Deemed Not To Literally Include FiberWire’s Braided PE, Then FiberWire Infringes Under the Doctrine of Equivalents

A. The Differences Between FiberWire’s PE and the Claimed First Fiber-Forming Materials Are Insubstantial

16. If “PE” as claimed in the 446 Patent is construed to mean “general purpose PE” (Arthrex Brf. on Claim Construction at 10, hereinafter “Arthrex Br.”), and it is found that FiberWire’s braided PE is not literally “general purpose PE,” then it is my opinion that there is infringement under the doctrine of equivalents because the differences between FiberWire’s braided PE and the first fiber-forming materials are insubstantial.

17. In a preferred embodiment, the 446 Patent describes the first fiber-forming materials as acting “as lubricating yarns” (Ex. 2 at 4:11-12). PE, including UHMWPE, is a lubricious material (Ex. 3 at 52:24-53:1). Further, the 446 Patent explains that the first set of yarns may be “non-absorbable polymers” (Ex. 2 at 4:10-11). UHMWPE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber-forming materials (Ex. 2 at 2:45-46). UHMWPE is a fiber-forming material. Therefore, the 446 Patent’s description of the first-fiber forming materials is consistent with UHMWPE. Moreover, UHMWPE is consistent with the more general description of the invention, as set forth in column 2, lines 40-63, column 3, lines, 21-28, 40-65, and column 6, lines 50-56.

18. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. 3 at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (*id.* at 51:15-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (*id.* at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (*id.* at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (*id.* at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. This just like the 446 Patent because the 446 Patent describes embodiments in which the first fiber-forming materials are lubricous and the second fiber-forming materials impart strength. Accordingly, FiberWire's braid is not, as Arthrex has suggested, the opposite of what is described in the 446 Patent.

19. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. 4 at 1:19-21; Ex. 3 at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. 3 at 26:24-27:6). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength. According to Arthrex's 234 patent, this problem was overcome by braiding UHMWPE with

polyester (Ex. 4 at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the “ability to approximate the tissue and hold it in place through biomechanical forces” (Ex. 3 at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester. Thus, Arthrex’s 234 Patent further shows that the differences are insubstantial because UHMWPE is described as a lubricous yarn that with bad knot properties, and similarly embodiments of the first fiber-forming materials are described as lubricous.

20. I understand that Arthrex has asserted that the differences between the first fiber-forming materials (if PE does not include UHMWPE) and UHMWPE are substantial because the purpose of UHMWPE in FiberWire is alleged to be to provide strength (Arthrex Br. at 11). I disagree with this statement because the 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. 2 at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire’s UHMW PE is lubricous (Ex. 3 at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, “to provide improved strength to the heterogeneous braid” (Ex. 2 at 4:33-36). FiberWire is consistent with this description; FiberWire’s PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. 3 at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,² of

² I use the term “knot pull strength” to refer to the force at which a suture having a knot tied in it fails when tested in a tension test. I use the term “knot holding strength” to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Exs. 26 and 27. Knot holding strength is an indication

the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot. Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

B. The Differences Between the Claimed First Fiber-Forming Materials And FiberWire's PE Are Insubstantial Based On the Function/Way/Result Analysis

21. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial under the function/way/result analysis.

22. I have used the "function/way/result" test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

of knot security. The 446 Patent describes another exemplary knot security test (Ex. 2 at 6:36-44).

23. In my opinion, the “function” of the first fiber-forming material is the same as the function of UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	Function of Limitation Under the Doctrine of Equivalents	Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

24. My opinion regarding the “function” of the first fiber-forming material is supported by the ‘446 Patent. The ‘446 Patent explains that the first fiber forming material is “dissimilar” to the second fiber and the braid of dissimilar yarns provides “outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns” (Ex. 2 at 2:50-52; 3:43-48). Further, the ‘446 Patent explains that it is possible to “tailor the physical” properties by “varying the type and proportion of each of the dissimilar fiber forming materials used” (*id.* at 2:58-61). Also, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (*id.* at 8:19-21).

25. It is my opinion that the UHMWPE in Arthrex’s FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid.

Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHMWPE and the flexibility of PET (Ex. 5 at 306:17-307:14; Ex. 6; *see also* Ex. 5 at 307:15-308:14; Ex. 7). Further, as I explained in my rebuttal report with respect to Mr. Grafton's work and Arthrex's 234 Patent, FiberWire's PE also provides lubricity and other surface properties that are different than PET, and PET when braided with PE in FiberWire increases the knot holding strength.

26. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	"Way" of Limitation Under the Doctrine of Equivalents	Way UHMWPE performs its Function in FiberWire™ and TigerWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Ex. 8 at 99-107).

27. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact. For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct intertwining contact" with a yarn from the second set (Ex. 2 at 2:40-44; *see also* 3:21-28; 3:40-45). The '446 Patent further explains that the heterogeneous braid properties are due to the "mechanical interlocking or weaving of the individual yarns" (*id.* at 2:56-58; 3:43-48). Also, during the

prosecution history, the applicants explained that the beneficial properties are due to the braiding of direct “intertwining” contact of dissimilar yarns (Ex. 9 at 2, emphasis original).

28. Further, the ‘446 Patent describes certain preferred embodiments in which the first fiber-forming materials act as lubricating yarns and the second fiber-forming materials provide strength (Ex. 2 at 4:9-59). The ‘446 Patent also describes other specific preferred embodiments that have PTFE braided in direct intertwining contact with PET to obtain the benefits of each yarn (*id.* at 7:1-8:61). These are all preferred embodiments where the at least one first-fiber forming material is braided in direct intertwining contact with at least one different, second fiber-forming material so that each yarn contributes to the heterogeneous braid. Because these are preferred embodiments, they are an example of the broader disclosed concept of braiding the first and second fiber forming materials, so that they can individually contribute to the overall properties of the heterogeneous braid. Notably, the invention is described more broadly than just these “preferred embodiments,” and, therefore, it is my opinion that neither the function, way, or result is limited to the specific properties of the first-forming material in any of the preferred embodiments.

29. It is my opinion that the UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products have the same “way” as the claimed first-fiber forming materials. My opinion is based on a visual inspection and observation of FiberWire™ and its manufacturing processes. In my opinion, at least one UHMWPE yarn in Arthrex’s FiberWire™ and TigerWire™ products is braided in direct intertwining contact with at least one PET yarn. My opinion is supported by Arthrex’s and Pearsalls’ testimony and documents. For example, Mr. Dreyfuss testified that the adjacent yarns in the FiberWire™ and TigerWire™ sheath are in direct intertwining contact with each other (Ex. 8 at p. 99-107).

30. In my opinion, the “result” of the first forming material is the same as the result of UHMWPE in Arthrex’s FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	“Result” of Limitation Under the Doctrine of Equivalents	Result of UHMWPE in FiberWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The result of the first set of yarns is to contribute to the heterogeneous suture braid a property different from the yarn in the second set, so that when they are braided the yarns contribute to the properties of the overall heterogeneous braid.	The result of the PE yarns is to provide a different property than the PET, so that when they are braided the PE yarns contribute properties to the overall heterogeneous braid.

31. My opinion regarding the “result” of the first-forming material is supported by the ‘446 Patent. For example, the ‘446 Patent explains that the “heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials” (Ex. 2 at 2:49-52). Further, the ‘446 Patent states that the “types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.” (*id.* at 6:52-56).

32. My opinion is that FiberWire™ and TigerWire™ suture products have the same claimed result. UHMWPE has and contributes properties that are different from those provided by PET. For example, Arthrex has admitted that the UHMWPE is added to FiberWire™ to increase strength. In FiberWire™, when the UHMWPE is braided with PET, it is my opinion that the UHMWPE contributes to the strength of the overall heterogeneous braid. Further, UHMWPE is known to have relatively high lubricity and has different lubricity than PET. Also, as I explained in my rebuttal report and through my declaration with reference to Arthrex’s 234 Patent, Mr.

Graftons' work, and the development of FiberWire, UHMWPE adds lubricity, pliability, and surface properties that are different than PET.

33. My opinion is further supported by the testimony and documents from Arthrex and Pearsalls witnesses:

Q What did you understand Mr. Grafton to mean when he said:

"Can you build a 25% Dyneema/75% polyester blend in Size 2 that is very flexible".
What did you understand that to mean?

A Yes, that he wanted a braid which was more -- not so stiff.

Q As the 100% ultra high molecular weight polyethylene?

A Yes. (Ex. 5 at 306:20-307:4, Ex. 6)

Q. Mr. Grafton wanted Pearsalls to braid polyester with the ultra high molecular weight polyethylene so that the polyester could provide flexibility?

A Yes. (Ex. 5 at 307:10-14, Ex. 6).

34. It is my expert opinion that both of the above documents and testimony demonstrate that Arthrex is "tailor[ing] the physical" properties of the braid by "varying the type and proportion of each of the dissimilar fiber forming materials used" as taught by the '446 Patent (Ex. 2 at 2:58-61).

C. I Disagree With Arthrex's Assertions Regarding the Purpose & Function of the First Fiber-Forming Materials

1. The 446 Patent Does Not State that the Only Function of the First Fiber-Forming Materials Is to Improve Pliability

35. I disagree with Arthrex's assertion that the only function of the first fiber-forming materials described in the 446 Patent is improving pliability. As I explained in my first report at ¶55 and my rebuttal report at ¶10, the 446 Patent describes a broader function for the first fiber-forming materials that is not limited:

- “heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which makeup the yarns” (*id.* at 2:49-52);
- “it is possible to tailor the physical . . . properties of the braid by varying the type and proportion of each of the dissimilar fiber forming used” (*id.* at 2:58-62);
- in preferred embodiments the first fiber-forming materials can contribute other properties including “pliability,” “compliance” and “surface lubricity” (*id.* at 4:11-13).

As I explained above, the properties of the first fiber forming materials are much broader than just pliability.

2. **The 446 Patent Does Not Describe the First Fiber-Forming Materials As “Relatively Weak”**

36. I disagree with Arthrex’s assertion that the 446 Patent describes the first fiber-forming materials as “relatively weak,” (Arthrex Br. at 11) and that this is a basis for finding that the differences between the first fiber-forming materials and FiberWire’s braided PE are substantial. I disagree because the 446 Patent does not describe the first fiber-forming materials as “relatively weak.” For example, the 446 Patent describes PE, which includes UHMWPE, as a first fiber-forming material, and UHMWPE was known to have certain strength attributes, such as tensile strength. Likewise, the 446 Patent describes polypropylene (PP) as a first fiber-forming material, and it is known to have certain strength attributes, namely tensile strength. This is described in the literature. For example, *Marks’ Standard Handbook for Mechanical Engineers*, a well known reference, describes polypropylene fibers as having a breaking tenacity of 4.0-7.0 gpd (Ex. 10). Further, U.S. Patent No. 4,413,110 describes certain polypropylene fibers as having a tenacity of at least about 8 gpd (Ex. 11 at 2:7-11). Also, the *Production and Applications of Polypropylene Textiles* states on page 54 that the breaking tenacity of polypropylene fibers is over 500 mNtex⁻¹ (Ex. 12). Thus, certain polyethylene and polypropylene fibers are not “weak”

in tensile strength. Thus, I disagree that the 446 Patent describes the first-fiber forming materials as being “weak.”

37. Arthrex seems to indicate that the first fiber-forming materials are all necessarily “weak” in tension when compared to the second fiber-forming materials and that only the second set of yarns can impart strength (Arthrex Br. at 11). Even assuming that Arthrex means weak in tension, I disagree with this statement. Arthrex’s statement is incorrect because polypropylene fibers, one of the first fiber-forming fibers, were known to have strength on the same order of magnitude of nylon and PET fibers, two of the second fiber-forming materials. For example, *Marks’ Handbook* describes polyester fibers, which I read as including PET, as having a breaking tenacity of 4.4-7.8 gpd, and nylon 6,6 fibers as having a breaking tenacity of 4.6-9.2 gpd (Ex. 10). Further, the *Production and Applications of Polypropylene Textiles* states on page 54 states that the breaking tenacity of polyester fibers, which I read as including PET, is 350 mNtex⁻¹ (Ex. 12). Using this information, PP has a breaking tenacity in the range of other well known relatively high-strength fibers such as polyester (PET) and nylon. Further, one fiber manufacturer describes the tensile strength of two first fiber-forming materials, PVDF and PP, as having about the same tensile strength as two of the second fiber-forming materials, nylon and PET. For example, it states that monofilament PVDF has a tenacity of 4.71 gpd, two monofilament polypropylenes have breaking strengths of 3.0 and 4.0 gpd, two monofilament polyesters (which I read as PET) as having a breaking strength of 4.5 or 6.0 gpd, and nylon monofilaments as having a breaking strength of 4.5-6 gpd (Ex. 13; *see also* Ex. 14). Consequently, the first fiber-forming materials are not all “weak” in tension in comparison to the second fiber-forming yarns, and it would be incorrect to read the 446 Patent as stating that only the second set of yarns imparts tensile strength, as Arthrex incorrectly suggests.

38. I understand that Arthrex asserts that “the admitted purpose of UHMWPE in FiberWire is to add strength to the braid” and implied that is UHMWPE’s only function (Arthrex Br. at 11). I disagree with this assertion because it is an oversimplification and a misunderstanding of the many different properties that a material can provide. As I explained in my rebuttal report at ¶¶24-27 and here above at ¶17, FiberWire’s PE is lubricous, and therefore it enhances other FiberWire properties such as handleability, pliability, and surface properties. Arthrex’s argument seems to attribute all of FiberWire’s strength to FiberWire’s PE. I disagree with this assumption. FiberWire’s PET also contributes to FiberWire’s strength properties, including knot holding strength properties (Ex. 4 at 1:24-26, 29; 2:50-52; Ex. 3 at 103:19-104:15). Further, even if FiberWire’s PE’s only function is to add tensile strength as Arthrex incorrectly asserts, it is my opinion that the first fiber-forming materials, such as PP and PVDF, function to add tensile strength. Therefore, the differences between UHMWPE and the first fiber-forming materials are insubstantial.

39. Also, Arthrex’s assertion that Ultra high molecular weight PE is “strong” is a simplification of material properties. Ultra high molecular weight PE is “weak” in at least two ways, compression and knot holding properties when braided in certain structures, which I explained above with reference to Mr. Grafton’s work and Arthrex’s 234 Patent. Thus, even if is Arthrex is correct (which it is not) that the 446 Patent describes the first fiber-forming materials as “weak” and braids made from them as weak, ultra high molecular weight PE satisfies these requirements because it too is “weak.”

D. Even if Arthrex is Correct Regarding the Teachings Of the 446 Patent, There Is Still Infringement Under the Doctrine of Equivalents

1. Even if Arthrex is Correct That The Function of the First Fiber-Forming Materials Is To Improve Pliability, FiberWire Infringes Because FiberWire's PE Improves Suture Pliability

40. I understand that Arthrex asserts that the only function of the first fiber-forming materials is to "improve overall pliability of the suture" and FiberWire's PE does not perform this function because it is a stiff material (Arthrex Br. at 10). For the reasons stated above, I disagree that this is the function of the first fiber-forming materials. But even accepting this function, there is still infringement under the doctrine of equivalents because FiberWire's braided ultra high molecular weight PE improves overall pliability of the suture. As I explained in ¶25 of my rebuttal report, ultra high molecular weight PE is lubricous and contributes to braid pliability because it allow the fibers to slide past each other when bent. In constructing FiberWire, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliability, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. UHMWPE has many uses. "General purpose" PE and UHMWPE can be substituted for each other, depending on the application.

41. Arthrex's argument appear to be based on confusing two discrete concepts, *material* stiffness and *braid* stiffness. *Material stiffness* is a material property that is dependent upon just the material properties, like the tensile and compressive moduli, and cross-sectional shape of the specimen, which in this instance is a fiber. In contrast, *braid stiffness* for a multifilament

structure like FiberWire is dependent upon many factors including the number of filaments, the modulus of elasticity in tension and compression, the fiber-to-fiber mobility, and the individual moment of inertia of each filament, the manner in which the materials are braided, and material lubricity. As the 446 Patent explains, material lubricity permits fiber-to-fiber mobility, so that when the braid is bent the fibers can easily bend and slide past other fibers. Thus, even accepting that ultra high molecular weight PE is “stiff,” Arthrex’s counsel assertions that it does not improve overall braid pliability are just wrong.

42. Arthrex’s argument is basically the same concept that I addressed before when Arthrex’s expert incorrectly assumed that FiberWire is a monofilament structure. As I explained previously, FiberWire is neither a monofilament nor a pure multifilament structure. Arthrex’s statement that FiberWire’s PE does not improve braid pliability basically makes a similar mistake and incorrectly assumes that FiberWire is a monofilament type structure.

IV. Under Arthrex’s Definition of “Consisting Essentially Of,” FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

43. As I understand the law, because the 446 Patent claims recite the phrase “consisting essentially of,” if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the “basic and novel characteristics” of the claimed suture. I understand that Arthrex contends that the “basic and novel characteristics” of the suture claimed in the 446 Patent are “a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties” (Arthrex Br. at 13). Arthrex asserts that that FiberWire’s coating materially affects this novel and basic characteristic because it materially affects handleability and knot tie down properties (Arthrex Br. at 13-14). I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties

described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a “material” affect on the basic and novel characteristics; and (iii) Dr. Burks’ tests and analyses show that FiberWire’s coating does not materially affect handleability. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

44. FiberWire’s coating does not materially affect FiberWire’s characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire’s coating is merely a surface “lubricant” (Ex. 15).

45. My opinion that FiberWire’s coating does not materially affect FiberWire’s PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex’s development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. 3 at 52:24-53:7). The

homogeneous UHMWPE braid was too lubricous to “hold a knot” (*id.* at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good “strength” properties (Ex. 3 at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (*id.* at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. 16). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. 16; Ex. 3 at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

- Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
- A. Yes.
- Q. Yes?
- A. Yes.
- Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
- A. Yes.
- Q. And when you say knot slippage, we're referring to this knot security test?
- A. Yes.
- Q. So are we using the terms knot slippage and knot security interchangeably here?
- A. You are, yes.
- Q. In your testimony?
- A. Yes.
- Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the

prototype; right?

A. Yes.

Q. And your idea was to add the PET and to improve the knot security?

A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. 3 at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. 3 at 68:25-70:12). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliability, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

46. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr. Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the [E]thicon sample)" (Ex. 6) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. 6). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

Q. I would like to know what you mean by in your

letter when you said, "If we can get this blend correct."
 You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?

- A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
- Q. Wait a second. You said optimization of two materials.
- A. (Witness nods head affirmatively).
- Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
- A. During -- during the -- during that period of time, yes.
- Q. So you were balancing off the properties of each material to try to get the optimum properties --
- A. Tensile strength.
- Q. To get the optimum tensile strength?
- A. (Witness nods head affirmatively).
- Q. What about knot security?
- A. Yes.
- Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
- A. Yes.
- Q. Any other properties? Knot tiedown?
- A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
- Q. So you were varying type and proportion of the materials to optimize all these properties in the product?
- A. Yes.

(Ex. 3 at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

- Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?
- A. All materials used.

(Ex. 17 at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

47. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasurable (Ex. 5 at 119:5-9; Ex. 8 at 94:2-9; Ex. 18 at 48:1-50:16; Ex. 19 at ARM002104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed³ and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters per minute (Ex. 5 at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. 5 at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. 5 at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. 5 at 95:14-17). The process is then repeated. I have measured

³ Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DMI Exhibits 284, 342, and 285, Exs. 20, 21, and 22, respectively). I determined that the linear density of DMI Ex. 284 (uncoated) is 2393 denier, DMI Ex. 342 (coated once) is 2474 denier, and DMI Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of DMI Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated DMI Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from DMI Ex. 342. Thus, the total pick-up of Ex. 285 over DMI Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Ex. 15).

48. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire

has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

49. I note that Arthrex does not address the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, Arthrex only asserts that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as Arthrex defined the novel and basic characteristics. Rather, the relevant issue as Arthrex framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Arthrex Br. at 13). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

50. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Arthrex, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Arthrex.

51. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties

attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns” (Ex. 2 at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (*id.* at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a “material” effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

52. I disagree with Arthrex that FiberWire’s coating has a “material” effect because Arthrex basically *excludes* coated sutures from the 446 Patent claims. But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to *further* improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. *Most preferably*, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating *may be* eliminated saving expense as well as avoiding the associated braid stiffening.

(*id.* at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire’s coating cannot be deemed to have a “material” effect on the basic and novel characteristics of the invention.

53. My opinion that FiberWire’s “coating” does not have a “material” effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Arthrex attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set

of continuous and discrete yarns (*id.* at 2:40-42). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (*id.* at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (*id.* at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. 8 at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. 2 at 2:45-48).

FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. 20, 21, and 22. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as is shown by its product development (Ex. 3 at 68:25-70:13).

The 446 Patent teaches "to tailor" the physical braid properties "by varying the type and proportion of each of the dissimilar fiber forming materials used" (Ex. 2 at 2:58-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. 3 at 68:25-70:13). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. 2 at 6:9-10). Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can "*further*" improve the handleability of the suture (Ex. 2 at 6:5-18) (emphasis added). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. 2 at 6:11-13). As shown by the SEM's of the FiberWire, the fibers are not bonded together (Exs. 20, 21 and 22). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

54. I further disagree with Arthrex's focus on FiberWire's coating with reference to defining what is "material" because the 446 Patent is not about "coating" or eliminating "coatings." Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. 2 at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (*id.* at 1:32-43), a PTFE coating (*id.* at 1:43-54), a monofilament like surface on a multifilament braid (*id.* at 1:55-2:2), and an elongated core (*id.* at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (*id.* at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

55. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties "attributable to the specific properties of the dissimilar fiber-forming materials" (*id.* at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be "improved" by a coating (*id.* at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent's description of the invention shows that it does not consider coating, as used on FiberWire, to have a "material" effect on the basic and novel characteristics of the claimed suture.

3. **Dr. Burks' Testimony Supports My Opinion that the Effects of FiberWire's Coating Are Not Material**

56. I have reviewed Dr. Burks' testimony and deposition transcript. I understand that he considered the differences between the treated and untreated sutures as "subtle" and "pretty close" (Ex. 23 at 87:7-13; 88:1-3; 96:18-19; 98:18-21). He also stated that he could not "clearly feel a difference" (*id.* at 88:9-10). This supports my opinion that any purported differences are not material.

57. Also, Dr. Burks testified that wearing gloves would make a difference in whether he, as a very experienced surgeon, can even tell the difference between the treated and untreated samples (*id.* at 96:24-97:5; 72:1-73:6). In fact, he testified that he may not have been able to tell a difference if he used just gloves (*id.* at 73:9-14; *see also* 96:24-97:5). He testified that using gloves made a difference in the feel of a suture (*id.* at 72:7-8). I understand from Dr. Burks that he wears gloves when using FiberWire in surgery (*id.* at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

58. I note that Arthrex criticizes for me for not remembering at my deposition that I had considered certain information in my analyses that Dr. Mukherjee had considered. But after reading Arthrex's criticism, I consulted my Rebuttal Expert Report and it refreshed my memory that I had considered those materials. As I explained in ¶54 of my rebuttal report, I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products with different coatings, different applications of coatings, and different suture constructions. Although I did not recall at my deposition that I had reviewed these documents, I do now recall reviewing them to determine

whether they discussed FiberWire's coating, and they do not. I have provided three reports in this case and reviewed thousands of pages of documents. My deposition was on July 26-27, 2006, just over three months since I finalized my rebuttal report. Although I did not recall that one paragraph from my three reports at my deposition, Arthrex's counsel did not ask me to review that paragraph when asking questions about these documents. If he had, it would have refreshed my memory on the issue.

V. Under Mitek's Definition of the Novel And Basic Characteristics, FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

59. I understand that Arthrex may contend that its FiberWire™ and TigerWire™ products do not infringe claim 1 because they have a coating of NuSil MED-2174. I further understand that the basis of Arthrex's argument is that the coating materially affects the basic and novel characteristics of the claimed invention. As I understand the argument, I disagree with it.

60. I understand that Mitek has asserted that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The addition of a coating on FiberWire™ and TigerWire™ does not have any material affect on these basic and novel characteristics. Regardless of the coating, FiberWire™ and TigerWire™ both still have a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. The coating is non-bioabsorbable and does not materially affect bioabsorbability of the yarns, does not materially affect at least one yarn from the first set being in direct intertwining contact with a yarn from the

second set, and the coating does not materially affect each yarn from contributing to the overall properties of the heterogeneous braid. Furthermore, Arthrex documents describe the coating as a lubricant (Ex. 26 at ARM001976).

61. The '446 Patent specifically contemplates, in the "Detailed Description of the Invention," that the braided sutures of the invention can be coated (Ex. 2 at 6:5-21). The '446 Patent describes the invention as including applying polymer coatings by making a solution of the polymer and a solvent, immersing the suture in the coating and solvent, and drying the suture (*id.* at 6:9-11). Thus, the '446 Patent's description of the invention as contemplating coatings supports my opinion that FiberWire™'s and TigerWire™'s coatings do not materially affect the novel and basic characteristics of the invention because the inventors specifically contemplated coated sutures. Notably, FiberWire™ and TigerWire™ are coated just as the '446 Patent describes; they are immersed in a solution of NuSil MED-2174 and a solvent and dried.⁴

62. Further, I have taken Scanning Electron Micrographs at the Materials Evaluation laboratory at the Philadelphia University Research Center of DMI exhibit 284 (uncoated), DMI exhibit 342 (coated once), and DMI exhibit 285 (coated twice) FiberWire™ suture braids. My Scanning Electron Micrographs are attached at Ex. 21 (DMI Ex. 284), Ex. 22 (DMI Ex. 342), Ex. 23 (DMI Ex. 285).

63. It is my expert opinion and observation from the above Micrographs that the coating on the FiberWire™ suture does not substantially permeate the braided structure and does not reside between the braid yarns.

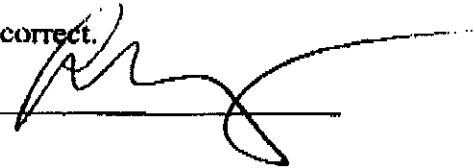
⁴ My opinion is further supported because the '446 Patent claims a "suture." I understand that most sutures are coated. Thus, the Patent claims clearly contemplate sutures having coatings, otherwise they would not cover many, if any, sutures.

64. It is my expert opinion and observation that the coating only appears on the surface of the braid.

I declare under penalty of perjury that the foregoing is true and correct.

Date Executed: September 1, 2006

/s/

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right, positioned over a horizontal line.

BROOKSTEIN DECLARATION EXHIBIT 1

David Brookstein, Sc.D.
Dean and Professor of Engineering
Philadelphia University
Philadelphia, PA 19144
(215) 951-2751

Curriculum Vitae

Education:

- Doctor of Science in the field of Mechanical Engineering, Minor Studies in Management from Sloan School of Management, Massachusetts Institute of Technology, 1976.
- Bachelor of Textile Engineering, Georgia Tech, 1971.
- Harvard University School of Business Summer Program on Research Management, 1990.
- Harvard University Graduate School of Education MLE Summer Program, 1998

Professional Experience:

Philadelphia University

1994 - Present

Dean and Professor of Engineering
School of Textiles and Materials Technology (soon
to be the School of Engineering and Textiles)

Chief academic and financial officer for a school with undergraduate majors in industrial and systems engineering, textile engineering (ABET accredited), textile technology, textile design, fashion design and fashion industry management. Master of Science programs are offered in textile engineering, textile design, textile marketing, global textile marketing, on-line MBA in textile and apparel marketing and fashion-apparel studies. Developed first Philadelphia University program, - Ph.D. in textile engineering and science. Principal Investigator for largest outside funded research grant received by Philadelphia University, \$2.7 million DoD grant for the Laboratory for Engineered Human Protection. Philadelphia University Program Leader for the National Textile Research Center, a \$10 million/annum grant for a consortium of universities that include Auburn University, Georgia Tech, North Carolina State University, Clemson University, UMASS-Dartmouth, Cornell University and University of California-Davis. Led the development of the Philadelphia University Research Center in the Manayunk section of Philadelphia.

Harvard University

2002 – 2003 Visiting Scholar

Harvard University Center for Textile and Apparel
Research (Division of Engineering and Applied Sciences)

Albany International Research Co. - Mansfield, MA

1992 - 1994 Associate Director

1983 - 1992 Assistant Director

1980 - 1982 Senior Research Associate

Directed all activities of the professional engineering group responsible for contract research, development, and manufacture of advanced composite materials and technical polymeric materials. Accomplishments include the invention and development of the multilayer interlock braiding system for producing three-dimensionally reinforced fibrous preforms for aerospace structures, the development of implantable biomedical devices such as vascular prostheses and orthopedic implants and the development of unique textile-based civil engineering structures. Engineering innovations led to 11 US patents and many other inventions protected by trade secret. Member of the senior management staff of the organization.

Northeastern University - Boston, MA

1981-1983 Adjunct Professor in Mechanical Engineering

Taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

Georgia Institute of Technology, College of Engineering

1975 - 1980 Assistant Professor of Textile Engineering

Taught and conducted research in the fields of textile and composites engineering with special emphasis on improving the energy efficiency of manufacturing systems. Obtained substantial funding from US DOE and US DOD. Active participant in College of Engineering co-op undergraduate programs.

Outside Professional Activities:

- Advisory Board of the College of Engineering, Georgia Tech.
- Member of the University City Science Center Research Provost Roundtable
- Adjunct Full Professor, North Carolina State University
- President, The Fiber Society (1996)
- Chairman, Textile Engineering Division-American Society of Mechanical Engineers (1994-1996)
- Research Associate - Textile Research Institute/Princeton
- Member of the Manufacturing Technology Operating Group of the ASME
- Peer Reviewer for ASME Fellows

Memberships:

- American Society for Engineering Education
- Council of Engineering Deans
- Institute of Industrial Engineers
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- American Conference of Academic Deans
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994,
- President (1996)
- SAMPE - Society for Advanced Materials and Process Engineering
- The Textile Institute

Awards and Honors:

- ASME – Fellow, 1995
- ASME - Textile Engineering Division, Chairman, 1980, 1994
- The Fiber Society - Fiber Society Lecturer, 1986-1987, 1993-1994, President, 1996
- The Textile Institute (United Kingdom) – Fellow, 1992
- Georgia Tech Academy of Distinguished Engineering Alumni, 1999
- Techtextil Innovation Prize, 1993 (Germany)
- ASTM Harold Dewitt Smith Award, 1998

Publications:

"Deductions about the False-Twist Process from Observations of the Variation of Torque on Detwisting at Heat Set Yarn," with Backer, S., and Thwaites, J.J., Journal of the Textile Institute, 67, p. 183-186, 1976.

"Transient Threadline Behavior in False-Twist Texturing," with Thwaites, J.J., and Backer, S., Journal of the Textile Institute, 67, 1976.

"Mechanics of Texturing Thermoplastic Yarns: Part III. Experimental Observations of Torsional Behavior of the Texturing Threadline for Pre-Drawn PET Yarns," with Backer, S., Textile Research Journal, 46, pp. 802-908, 1976.

"Mechanics of Texturing Thermoplastic Yarns: Part V. Steady State Mechanics of Drawing Texturing," Textile Research Journal, 47, p. 256-266, 1977

"Material-Process Interactions During False-Twist Texturing," with Backer, S., Journal of Applied Polymer Science: Applied Polymer Symposium, 31, p. 63-82, 1977.

"Mechanics of Texturing Thermoplastic Yarns: Part VI. Transient Mechanics of Draw Texturing," with Backer, S., Textile Research Journal, 48, p. 198-218, 1978.

"On the Mechanics of Draw Texturing," Journal of Applied Polymer Science: Applied Polymer Symposium, 33, p. 197-202, 1978

"Energy Consumption and Conservation: Textile Drying," ACS Symposium Series, 107/17, 1979

"All That Glitters is Not Gold," Textile World, October 1979

"Energy Conservation in the Textile Industry," ERDA - Phase I Report, DOE, April, 1977, Quarterly Reports, 1976 to 1977, Final Report.

"Processing of Pitch-Based Staple Carbon Fiber," Union Carbide Corporation, November 1977, Final Report.

"Low Thermal Conductivity of PAN-Based Carbon Fiber, Hercules, Inc., Monthly Reports and Final Report

"Development and Demonstration of Energy-Conserving Drying Modifications to Textile Processes," U.S. DOE Monthly Reports.

"Optimization of Sucker Rod Pumping Using Novel Material-Systems Concepts," with Skelton, J. and Dent, R., Proceedings of the Sixth Symposium of Engineering Applications of Mechanics, Petroleum Society of CIM, 1982

"Mechanical Characterization of Braided Cylinder," with Tsiang, T.H., and Dent, J., Proceedings of the 29th SAMPE Meeting, 1984.

"Design and Development of a High Stability Truss Chord," with Helmke, R., and Kominos, C., Proceedings of the 30th SAMPE Meeting, 1985.

"Load-Deformation Behavior of Composite Cylinders with Integrally-Formed Braided and Machined Circular Holes," with Tsiang, T.H., Journal of Composite Materials, 19, September 1985.

"Braided Composites: Attachment Considerations, Proceedings of the Composites in Manufacturing, Los Angeles, CA, January 1986.

"Foam Assisted Drying,: with Skelton, J., Petterson, D.R., and Lauchenauer, F., Proceedings of the International Drying Symposium, Cambridge, MA, August 1986

"Joining Methods of Advanced Braided Composites," Composite Structures, 6, p. 87-95, 1986

"Structural Applications of Advanced Braided Composites," Proceedings of the SPE Advanced Polymers Composites Division, November 1988.

"Processing Advanced Braided Composite Structures," Proceedings of the WAM of ASME, Materials Division, November 1988.

"Interlocked Fiber Architecture: Braided and Woven," Proceedings of the 35th SAMPE Meeting, April, 1990.

"Evolution of Fabric Preforms for Composites," Journal of Applied Polymer Science: Applied Polymer Symposium, 47, p. 487-500, 1991.

"A Comparison of Multilayer Interlocked Braided Composites with Other 3-D Braided Composites," 3rd International Techtextil Symposium, 14-16, May 1991, Frankfurt.

"On the Mechanical Behavior of 3-D Multilayer Interlock Braided Composites," with Preller, T., and Brandt, J., DASA-Deutsche Aerospace, Proceedings of NASA Fiber-Tex '92.

"The Evolution of 3-D Composites," Fifth European Conference on Composite Materials, 7-10 April 1992, Bordeaux.

"The Solid Section Multilayer Interlock Braiding System," 4th International Techtextil Symposium, 4 June 1992, Frankfurt.

"On the Mechanical Properties of Three-Dimensional Multilayer Interlock Braided Composites, TECHTEXTIL Symposium, 1993, Frankfurt.

"3-D Braided Composites-Design and Applications," Sixth European Conference on Composite Materials, 20-24 September 1993, Bordeaux

"Concurrent Engineering of 3-D Textile Preforms for Composites," International Journal of Materials and Product Technology, Vol. 9, Nos 1/2/3, 1994.

"Advanced Textile Airbeams for Temporary Shelters, 6th TECHTEXTIL Symposium, 1994, Frankfurt.

"Physical Properties of Twisted Structures" with Ning Pan, Fiber Society Symposium, Asheville, NC, 1998.

PATENTS Consisting of Original Contributions to field of engineering:

1. U.S. Patent 4,290,170 "Device for Aligning and Attenuating Fiber Mats," A device for producing aligned carbon fiber webs for use in composites.
2. U.S. Patent 4,497,866 "Sucker Rod," An elliptical cross-section braided composite rod for pumping oil.
3. U.S. Patent 4,602,892 "Sucker Rod," A braided composite rod and coupling for pumping oil.
4. U.S. Patent 4,841,613 "Pressure Developer or Press Roll Containing Composite Material," A composite press roll with variation of radial stiffness.
5. U.S. Patent 4,909,127 "Braiders," A braider with non-circular braider tracks and a unique package carrier for use with braider.
6. U.S. Patent 5,004,474 "Prosthetic Anterior Cruciate Ligament Design," An artificial ligament device having a tubular woven ligament and being adapted for joining the ends of two bones.
7. U.S. Patent 5,357,839 "Solid Braid Structure" A 3-D system for producing braids.
8. U.S. Patent 5,358,758 "Structural Member" A fiber reinforced structural member produced from a complex woven fabric.
9. U.S. Patent 5,411,463 "Composite Roll and Method of Making" A fiber reinforced roll for papermaking.
10. U.S. Patent 5,501,133 "Apparatus for Making a Braid Structure" A novel manufacturing system for producing 3-D multilayer interlock braided textile and fiber reinforced composite structures.
11. U.S. Patent 5,697,969 "Vascular Prosthesis and Method for Implanting" A fibrous synthetic vascular graft with a combination of resorbable and non-resorbable layers.

Non-patentable trade secret inventions developed at Albany International Research Co.

1. Fiber-reinforced composite rocket igniter for Small ICBM and Pegasus Air-Launched Vehicle
2. Specialty vascular grafts and bio-absorbable orthopedic implants
3. Flexible air-beam for military structures
4. New method for drying paper during the papermaking process
5. Complex, reduced delamination rocket motor exit cones

BROOKSTEIN DECLARATION EXHIBIT 2



US005314446A

United States Patent [19]**Hunter et al.**[11] **Patent Number:** **5,314,446**[45] **Date of Patent:** **May 24, 1994**

- [54] **STERILIZED HETEROGENEOUS BRAIDS**
- [75] **Inventors:** Alastair W. Hunter, Bridgewater;
Arthur Taylor, Jr., Plainfield, both of
N.J.; Mark Steckel, Maineville, Ohio
- [73] **Assignee:** Ethicon, Inc., Somerville, N.J.
- [21] **Appl. No.:** 838,511
- [22] **Filed:** Feb. 19, 1992
- [51] **Int. Cl.³** D04C 1/00
- [52] **U.S. Cl.** 606/231; 606/228;
87/7; 87/9; 428/370
- [58] **Field of Search** 606/228, 230, 231;
87/7, 8, 9; 428/225

[56] **References Cited****U.S. PATENT DOCUMENTS**

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136

4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A51F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes*Assistant Examiner*—Chris Raimund*Attorney, Agent, or Firm*—Hal Brent Woodrow[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

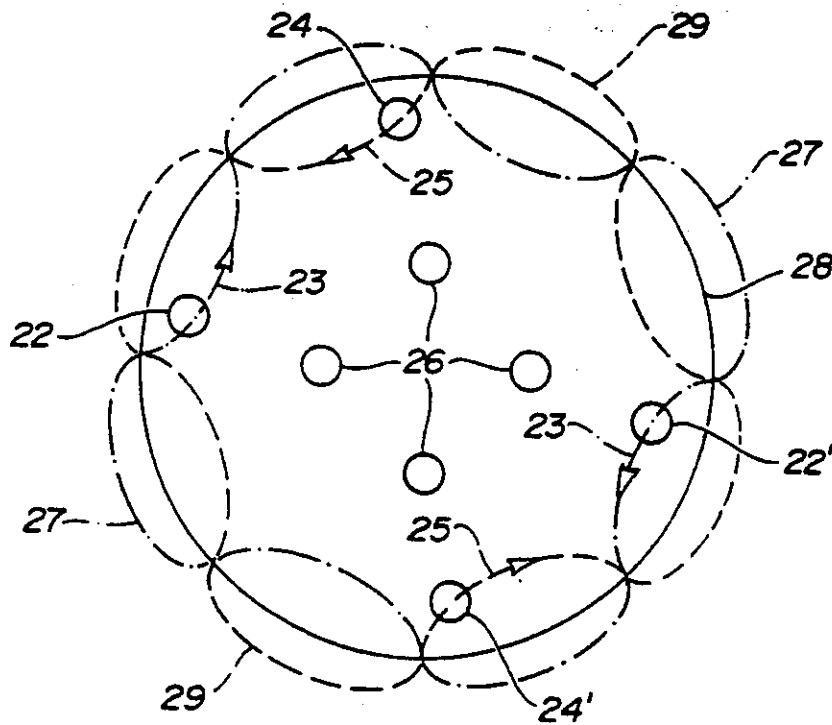
U.S. Patent

May 24, 1994

Sheet 1 of 3

5,314,446

FIG-1



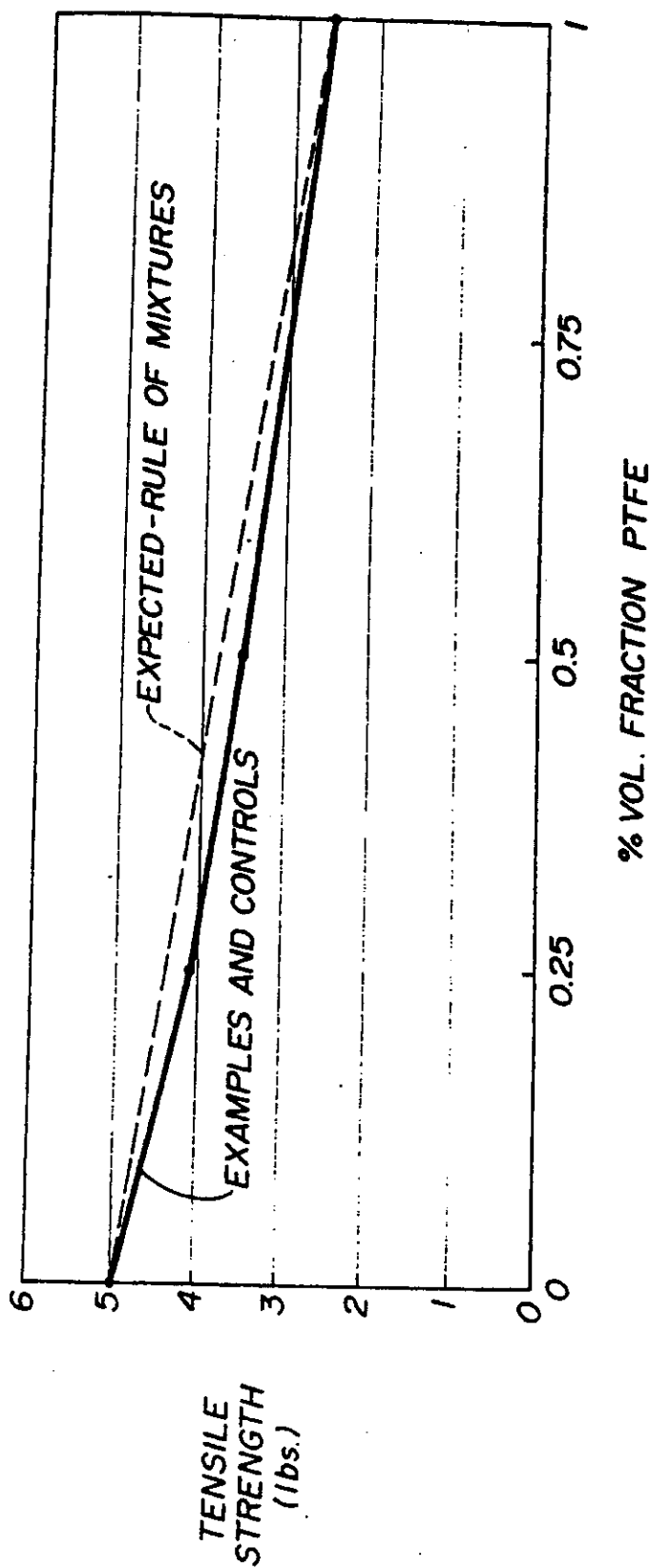
U.S. Patent

May 24, 1994

Sheet 2 of 3

5,314,446

FIG-2



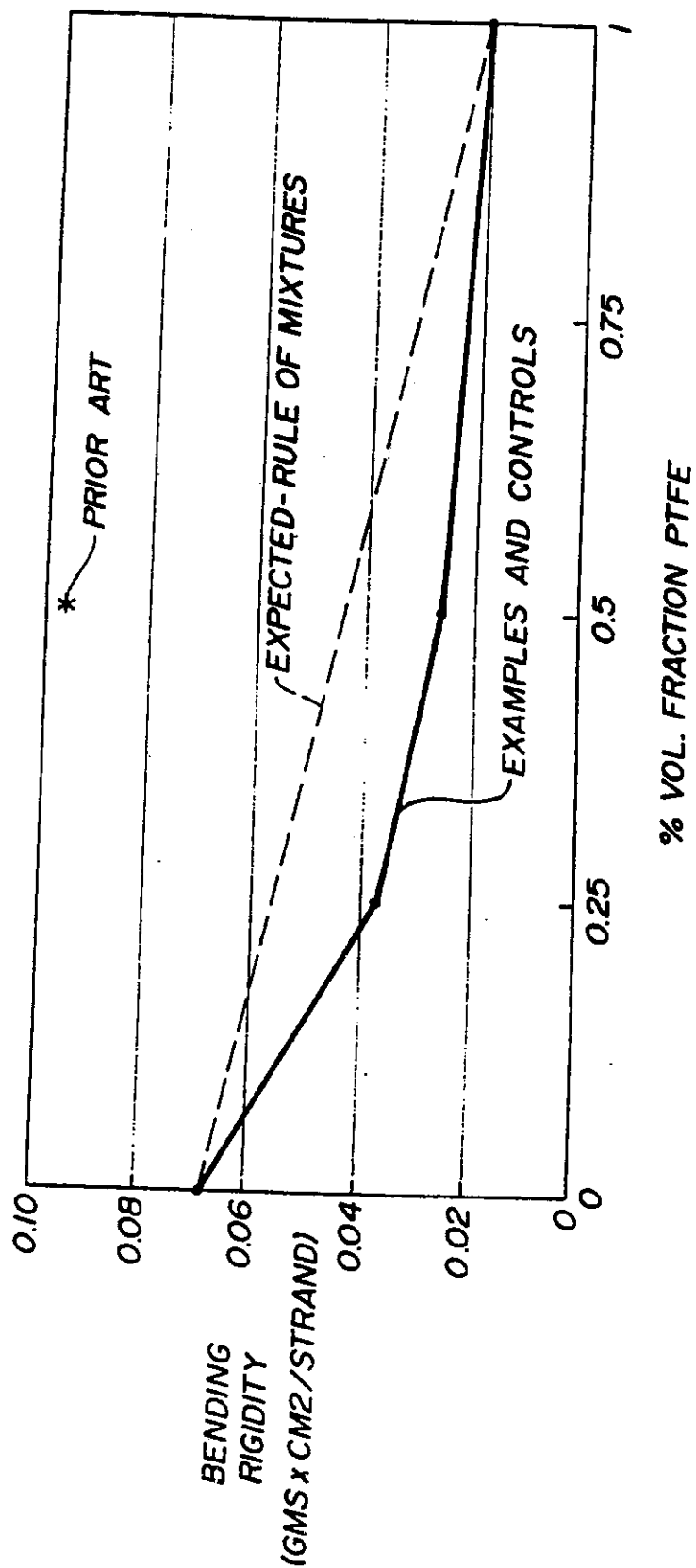
U.S. Patent

May 24, 1994

Sheet 3 of 3

5,314,446

FIG-3



1

5,314,446

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

2

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricious polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

3

5,314,446

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

4

ϵ -caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Dekker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychloroethylenes, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

5

5,314,446

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

6

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

7

5,314,446

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider

8

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm ²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.35	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (V_f/a) (P_a) + (V_f/b) (P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and V_f/a and V_f/b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the bending moment-radius of curvature plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table I and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

5,314,446

9

- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
 - b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
 - c) optionally a core.
2. The surgical suture of claim 1 wherein the suture is attached to a needle.
 3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.
 4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.
 5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

10

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.
7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.
8. The surgical suture of claim 1 wherein the second set of yarns is PET.
9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.
10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.
11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.
12. The surgical suture of claim 8 wherein the suture is attached to a needle.

20

* * * * *

25

30

35

40

45

50

55

60

65

BROOKSTEIN DECLARATION EXHIBIT 3

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS

3 DePuy Mitek, Inc., a
4 Massachusetts Corporation,

5 Plaintiff,

6 vs.

CIVIL ACTION
NO. 04-12457 PBS

7 Arthrex, Inc., a Delaware
8 Corporation,

9 Defendant.

10 DEPOSITION OF:

DONALD GRAFTON

11 DATE:

March 14, 2006

12 TIME:

8:38 a.m. to 1:23 p.m.

13 LOCATION:

The Ritz Carlton Golf Resort
2600 Hibouron Drive
Naples, FL 34112

14 TAKEN BY:

Plaintiff

15 REPORTER:

Deborah A. Krotz, RPR, CRR

16 VIDEOGRAPHER:

Gene Howell, CLVS

<p>22</p> <p>1 Q. And you don't recall whether or not the polyester 2 suture from Arthrex had a core?</p> <p>3 A. You said from Arthrex. You're talking about 4 Pearsalls now?</p> <p>5 Q. I'm sorry. The 100 percent polyester suture from 6 Pearsalls, did it have a core?</p> <p>7 A. Don't know.</p> <p>8 Q. Don't know? And the polyester that was braided 9 in the polyester suture from Pearsalls, do you know what 10 type of polyester that was?</p> <p>11 A. No.</p> <p>12 Q. When's the first time that you went over to 13 England to visit Pearsalls?</p> <p>14 A. Don't remember.</p> <p>15 Q. How many times have you been over to England to 16 visit Pearsalls?</p> <p>17 A. Three to five.</p> <p>18 Q. When you were involved in the process of 19 selecting this polyester suture from Pearsalls, did you go 20 over and visit Pearsalls?</p> <p>21 A. No.</p> <p>22 Q. No? At some point, Arthrex -- Let me back up. 23 What was the next suture that you can remember 24 Arthrex selling after the polyester?</p> <p>25 A. Jenzyme Tevdek.</p>	<p>24</p> <p>1 Q. Knot tiedown? Is that one of the considerations?</p> <p>2 A. Knot -- knot strength.</p> <p>3 Q. Was knot tiedown one of the considerations 4 that --</p> <p>5 A. Well, obviously, if you are going to tie a knot, 6 I mean, it's going to be tied down to something. Yes. 7 The makeup of the suture anchor, so, yes.</p> <p>8 Q. So the answer is yes?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. When you were selecting the Pearsalls 11 suture, was knot strength a consideration?</p> <p>12 A. Of course.</p> <p>13 Q. And when you were selecting the Pearsalls suture, 14 was tensile strength a consideration?</p> <p>15 A. Yes.</p> <p>16 Q. When you were selecting the Pearsalls suture, was 17 knot tiedown a consideration?</p> <p>18 A. Knot tiedown, knot strength are -- in my thinking 19 are similar or the same thing.</p> <p>20 Q. Same thing?</p> <p>21 A. (Witness nods head affirmatively).</p> <p>22 Q. What do you mean -- In your thinking, when you 23 say knot strength, what do you mean?</p> <p>24 A. Surgeon's application is to tie a knot. That is 25 affixing it to -- in approximation to tissue to bone.</p>
<p>23</p> <p>1 Q. Were you involved in the selection of the Tevdek 2 suture?</p> <p>3 A. What do you mean involved? Primary 4 identification or selection or did I know the company? Or 5 you are going to have to -- When you say involved, sir, I 6 need to know exactly what you're talking about.</p> <p>7 Q. Okay. Were you involved in the selection of this 8 Tevdek suture from Jenzyme?</p> <p>9 MR. SOFFEN: Objection; vague. He just said he 10 doesn't have --</p> <p>11 A. I'm not sure -- Again, when you say involved, I'm 12 involved in this, but I'm not asking the questions. So 13 you need to -- when you say involved, what does involved 14 mean exactly? I -- I was the engineer that was 15 responsible for saying yes, this is a product that meets 16 engineering specifications.</p> <p>17 Q. Okay. Did you recommend that Arthrex sell the 18 Tevdek sutures?</p> <p>19 A. From an engineering standpoint, the material met 20 the specification or engineering requirements to be used 21 with a suture anchor.</p> <p>22 Q. And what were the engineering requirements that 23 you reviewed Tevdek suture for?</p> <p>24 A. Knot strength, tensile strength, color, 25 biocompatibility. You know. It's -- on and on.</p>	<p>25</p> <p>1 That is knot tiedown. And there's a knot placed in the 2 suture, so -- so tying a knot and knot tiedown are the 3 same things as far as I'm concerned.</p> <p>4 Q. Okay. You just said tying a knot and knot 5 tiedown is the same thing. My question was slightly 6 different. Knot strength versus -- What is your 7 understanding of knot strength?</p> <p>8 A. It's the mechanical tensile of the suture's 9 ability to -- to, after tying a knot, before breakage.</p> <p>10 Q. Did you generally consider knot strength to be 11 determined by tying a knot in a suture and testing it on a 12 tensile --</p> <p>13 A. Yes.</p> <p>14 Q. -- testing machine?</p> <p>15 A. Yes.</p> <p>16 Q. How about knot tiedown? Is that --</p> <p>17 A. We didn't test for knot tiedown.</p> <p>18 Q. So you -- Before, you said knot strength and knot 19 tiedown were the same thing.</p> <p>20 A. That's why I said that we tested for knot 21 strength -- okay -- for -- of tying a knot. And I 22 consider those the same things. So we didn't -- we didn't 23 test specifically for tying soft tissue down. We tested 24 the knot as tying a knot versus -- what the standard calls 25 for and doing a pull test on it.</p>

26

1 Q. Let me back up to make sure this is clear. Knot
2 strength versus knot tiedown. In your mind, are they the
3 same thing or are they different?
4 A. I'm not sure I understand your question. Say
5 that again.
6 Q. Sure. Knot strength --
7 A. Mmm-hmm (affirmative).
8 Q. -- which I think you testified that you
9 understood to be tying a knot in a suture and pulling it
10 on a tensile machine -- tensile tester machine to
11 determine the strength at which the knot will break;
12 right?
13 A. Yes.
14 Q. Okay. Then there's another term called knot
15 tiedown, and I'm trying to understand whether, in your
16 mind, you think that's the same as knot strength or do you
17 use that term to mean something else?
18 A. They're closely related.
19 Q. And how are they related?
20 A. When you have a knot tiedown, you've tied a knot.
21 The strength of the knot is going to affect the ability to
22 hold -- to approximate the tissue in the tiedown area that
23 you're talking about.
24 Q. If the knot had a good tiedown or a bad tiedown,
25 what do you mean by that?

27

1 A. Its ability to approximate the tissue and hold it
2 in place through biomechanical forces.
3 Q. So that's related to knot strength, but it's not
4 necessarily the same thing; is that the way you're using
5 the term?
6 A. Yes.
7 Q. The way I heard you describe knot tiedown was you
8 said the ability to approximate the tissue and hold it
9 into place through biomechanical forces.
10 A. (Witness nods head affirmatively).
11 Q. When you say ability to approximate the tissue,
12 what do you mean by that?
13 A. Shift tissue in the position that the surgeon
14 would like for it to be on the bone.
15 Q. Shift tissue; did you say?
16 A. Yes.
17 Q. S-H-I-F-T?
18 A. Yes.
19 Q. So the knot's moving the tissue?
20 A. The suture is holding -- the suture loop with the
21 knot in it, is holding the tissue in the position that the
22 surgeon would like for it to be on bone.
23 Q. That's taking the place of the tissue? When you
24 say approximate the tissue, how is it approximating
25 tissue?

28

1 A. It's -- The tissue is here. The location the
2 surgeon wants it here. The suture loop as it is tied
3 moves the tissue into position.
4 Q. Holds it there?
5 A. Yes.
6 Q. And what -- what biomechanical forces were you
7 referring to?
8 A. Forces on the glenohumeral joint.
9 Q. In a knot strength test, it's the forces are
10 being applied and generally in one direction; correct?
11 A. Yes.
12 Q. The biomechanical force that you are referring to
13 in this knot tiedown, the forces are coming from different
14 directions; right?
15 A. Yes.
16 Q. Okay. When you are referring to knot tiedown
17 then, you're referring to -- you're referring to it in a
18 sense as a strength?
19 A. Are you finished? Is that the question?
20 Q. Right.
21 A. I don't believe -- Say it again then.
22 Q. Sure. Knot tiedown, the way you're referring to
23 it, it's a strength then? It's kind of like -- because
24 knot strength would be measured in p.s.i.
25 A. I said that's one of the attributes of it.

29

1 That's not the total attribute of it. I mean it's to
2 approximate tissue into position is knot tiedown.
3 Q. Well, what else would be included?
4 A. I just told you. Approximate tissue, strength.
5 Q. So the strength would -- I understand the --
6 A. The size of the knot bundle. You know, there's
7 --
8 Q. Size of the knot bundle?
9 A. Yes.
10 Q. What do you mean by that?
11 A. How large the knot is once it has been tied and
12 cut.
13 Q. So knot tiedown includes the size of the knot
14 bundle?
15 A. Yes. You know, the knot tiedown -- I want to say
16 this -- that's not a term that we specifically use, so
17 it's a little bit foreign. I mean I don't -- I've never
18 had a surgeon ask me about knot tiedown.
19 Q. Okay.
20 A. So I didn't -- your -- I'm not sure where you're
21 going with this, but there's -- we did knot testing and we
22 did straight pull testing of the suture so that your knot
23 tiedown, I'm -- I'm not real sure what you're asking for
24 there. I --
25 Q. Well --

<p>42</p> <p>1 A. What's the date on this?</p> <p>2 Q. The date on this is -- the last page is dated</p> <p>3 November 4th, 2005.</p> <p>4 A. Okay. I want to quantify this then, because</p> <p>5 you're talking about a time period after I worked for the</p> <p>6 company, so when you -- when it says in here that I'm</p> <p>7 familiar with these products, it would be at the time I</p> <p>8 had left the company. And this is -- this was written</p> <p>9 after I left the company. So I can't totally say that I</p> <p>10 am familiar with those products under that.</p> <p>11 Q. So you would agree that you were familiar with</p> <p>12 the state-of-the-art for surgical suture products as of</p> <p>13 the date you left Arthrex?</p> <p>14 A. Define state-of-the-art, sir.</p> <p>15 Q. State-of-the-art? Well, the general -- You don't</p> <p>16 have an understanding of what that means?</p> <p>17 A. I want to understand what you mean in the context</p> <p>18 of this state-of-the-art.</p> <p>19 Q. Okay.</p> <p>20 A. I mean there's -- there's -- there's --</p> <p>21 Q. This is from Pearsalls, so I can't tell you</p> <p>22 exactly what they mean, so ... Let me back up. When you</p> <p>23 were --</p> <p>24 A. I was -- I was familiar with the competitive</p> <p>25 products on the market and what we offered and how they</p>	<p>44</p> <p>1. and tensile strength; right?</p> <p>2 A. Yes.</p> <p>3 Q. Didn't that come up in your testing?</p> <p>4 A. I don't recall.</p> <p>5 Q. What was your involvement in the development of</p> <p>6 FiberWire?</p> <p>7 A. It was my idea.</p> <p>8 Q. When you say it was your idea, what do you mean</p> <p>9 by that?</p> <p>10 A. I'll give you -- Would you like the story on how</p> <p>11 FiberWire came about?</p> <p>12 Q. Sure.</p> <p>13 A. We were having issues from customers with the</p> <p>14 Tevdek suture being low tensile strength as compared to</p> <p>15 competitors' suture anchors with suture, primarily</p> <p>16 Ethicon.</p> <p>17 Q. Ethibond?</p> <p>18 A. Ethibond. This was numerous complaints from</p> <p>19 friendly surgeons, not -- not a massive amount of</p> <p>20 complaints, but it was determined that the tensile</p> <p>21 strength of the suture was not as good as the Ethicon</p> <p>22 Ethibond suture.</p> <p>23 Q. When you say friendly, do you mean friendly to</p> <p>24 Arthrex?</p> <p>25 A. Yes. And I had gotten a phone call from a Dr.</p>
<p>43</p> <p>1 compared to the competitive products.</p> <p>2 Q. Okay. And that was as of the date you left</p> <p>3 Arthrex?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And how long were you familiar with</p> <p>6 Arthrex's suture products and the competitive suture</p> <p>7 products that are in the marketplace?</p> <p>8 A. When we started marketing the product, the</p> <p>9 sutures, until the time I left.</p> <p>10 Q. Okay. So sometime when Arthrex began selling the</p> <p>11 suture from the supplier from New Mexico?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. When Arthrex shifted from the Pearsalls</p> <p>14 suture to the Tevdek suture, was there any consideration</p> <p>15 to -- or for Arthrex designing its own suture?</p> <p>16 A. No.</p> <p>17 Q. Why not?</p> <p>18 A. Because we could find a suture OEM that was</p> <p>19 available already. Why manufacture the suture when</p> <p>20 there's a readily available source?</p> <p>21 Q. Now you said you tested for the Tevdek suture</p> <p>22 before it was selected; right?</p> <p>23 A. Of course.</p> <p>24 Q. And then it came back after it was selected, the</p> <p>25 response from surgeons was that it had low knot strength</p>	<p>45</p> <p>1 Deberdino who was a surgeon at Fort Sam Houston, San</p> <p>2 Antonio. His -- his comments were that he had tied three</p> <p>3 knots the previous afternoon using the FASTak product of</p> <p>4 Arthrex -- that's a glenoid labrum device -- and had broke</p> <p>5 the knots on all three of them. And -- you know -- he</p> <p>6 said it kind of jokingly. He said, "And I didn't even</p> <p>7 work out the day before."</p> <p>8 And so he was trying to be nice about it, but</p> <p>9 bottom line was your suture sucks. Okay?</p> <p>10 And so -- you know -- we're in a position where</p> <p>11 we need to find a suture that will be competitive. I had</p> <p>12 been to Pearsalls many times working on bioabsorbable</p> <p>13 products. This was the time that you referred to earlier</p> <p>14 where I said three to five, and was familiar with suture</p> <p>15 manufacturing, the steps required to manufacture a suture.</p> <p>16 One of the trips there, Mr. Lyon had pointed out</p> <p>17 to me a -- the other products they manufactured, which was</p> <p>18 fishing line and silk used in decorated drapes. The</p> <p>19 fishing line used a ultra-high molecular weight</p> <p>20 polyethylene material that was very strong, and I -- at</p> <p>21 some point, it was decided that we would try some of that</p> <p>22 for a suture.</p> <p>23 I had Pearsalls, mainly through Brian, as being</p> <p>24 the manufacturing person --</p> <p>25 Q. Brian Hallett?</p>

12 (Pages 42 to 45)

<p>46</p> <p>1 A. That's correct -- make some Size 2 braided 2 material, send to me, and at the -- coincidentally, at the 3 same time, I had a Dr. Steve Burkhart from San Antonio and 4 a Dr. Casey Chan, who is a R & D guy in knot testing and 5 suture. They were -- they were at Arthrex at the time 6 when this material showed up. 7 We tested the material. The strength was 8 excellent. The knot slippage was very poor, would not 9 hold a knot. 10 So at that point in time, it looked like we would 11 not be able to use an alternative material of ultra-high 12 molecular weight polyethylene because the slippage of the 13 material -- because of the slippage of the material tested 14 with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at 15 that point in time, the -- the product was -- was on hold. 16 I was on a trip to Chicago to the national sales 17 meeting, and I had this idea of adding PET to the 18 ultra-high molecular weight polyethylene to enhance the or 19 reduce the knot slippage of the product. I sent an e-mail 20 to Dr. Steve Burkhart and suggesting that since he was 21 familiar with the testing we had done very recently with 22 just the ultra-high molecular weight PE, of adding the 23 PET, and his -- I'll never forget the e-mail. He thought 24 that was a killer idea. 25 And so I had asked then at that time for Brian</p>	<p>48</p> <p>1 processed to make a braid. 2 Q. Okay. And how many times were you over in 3 England? 4 A. I told you already. Three to five. 5 Q. Three to five. 6 A. Approximate. 7 Q. Is that total lifetime? 8 A. That's an approximate number total lifetime, yes. 9 Q. Have you been to other manufacturing facilities 10 for sutures? 11 A. Jenzyme Tevdek. 12 Q. And how many times have you been there? 13 A. Once, I believe. 14 Q. And when you were at Jenzyme Tevdek, did you see 15 the manufacturing processes for Tevdek? 16 A. It was a dog and pony quick courtesy through the 17 facility. 18 Q. So when you came up with the idea for using 19 ultra-high molecular weight polyethylene in a suture, did 20 you -- you say you are familiar with how sutures are made? 21 A. I'm also a fisherman. There's -- you know -- 22 fishing line is -- uses ultra-high molecular weight 23 polyethylene as a material that's used for sport fishing, 24 very high strength. 25 Pearsalls made fishing line. And so they had</p>
<p>47</p> <p>1 Hallett to make me samples up of using those two materials 2 and -- and send to me. And we tested the materials, and 3 now we had a product that had superior tensile strength 4 and greater knot strength than any competitive product out 5 on the market. 6 Q. Okay. If I could just back up to a couple of 7 points that you mentioned to make sure I understand what 8 happened here. The -- You said the idea began -- or I'm 9 sorry. Back up. You said when this idea came up, you had 10 already been to Pearsalls several times? 11 A. Mmm-hmm (affirmative). 12 Q. And you were familiar with -- 13 A. Yes. 14 Q. And when this idea came up, you were familiar 15 with how sutures were manufactured? 16 A. Yes. 17 Q. Okay. And what did you mean by that? 18 A. One of the products -- projects that I worked on 19 was a bioabsorbable suture similar to what Ethicon sells 20 as Panacryl, and the difference being this was 100 percent 21 PLLA material. The -- so we worked on this for about a 22 year -- I don't know the exact time -- with many trips 23 over to Pearsalls to change the construct of the yarn to 24 enhance the tensile properties of the material. And so at 25 that time, I became familiar with how a suture is</p>	<p>49</p> <p>1 this material already available as a fishing line. So it 2 was an easy conversion -- you know -- conclusion, 3 conversion to say what if this is used as a suture 4 material, because ultra-high molecular weight polyethylene 5 is a totally inert material. 6 Q. When you saw that Pearsalls had been using 7 ultra-high molecular weight polyethylene in fishing 8 line -- 9 A. Yes. 10 Q. -- do you know how it was being used in fishing 11 line, what the construction was? 12 A. No. 13 Q. Was it a braided construction? Was it -- 14 A. I can't tell you for sure, sir. 15 Q. You don't know? 16 A. I wasn't interested in buying fishing line, so I 17 didn't look at the details of it. 18 Q. So you had -- Sitting here today, you can't tell 19 me anything at all about how the fishing line that 20 Pearsalls was making with ultra-high molecular weight 21 polyethylene was constructed? 22 A. It went through their manufacturing processes in 23 their company, but specifically how it was made, the 24 constructs, I have no idea or the size. 25 Q. In other words, you have no idea if it was all</p>

<p>1 ultra-high molecular weight polyethylene or if it was 2 braided or -- 3 A. It's been too long ago. I can't tell you that. 4 Q. And your idea was to use the ultra-high molecular 5 weight polyethylene as a suture? 6 A. Yes. 7 Q. Okay. And you had Mr. Hallett make a Size 2, I 8 think you said? 9 A. Yes.. 10 Q. Okay. Can you describe the construction of that 11 first -- 12 A. I don't remember now. It's been too long. 13 Q. Was it all ultra -- ultra-high molecular weight 14 polyethylene? 15 A. Initially, yes, as a test prototype material. 16 Q. Was it braided? 17 A. Yes. 18 Q. Was it an eight-carrier or a sixteen-carrier? 19 A. I don't remember. 20 Q. You said it was a Size 2 though? 21 A. Yes. 22 Q. So it was a Size 2 ultra-high molecular weight 23 polyethylene braided suture that did not have PET? 24 A. For the initial prototype material, that's 25 correct.</p>	<p>50 1 Q. Knot security test? 2 A. Yes. 3 Q. Was that the test we drew in Exhibit Number 421? 4 A. That's correct. 5 Q. Okay. And you said the strength was excellent, I 6 believe, of the initial prototype, but the knot slippage 7 was poor; is that right? 8 A. Yes. 9 Q. Okay. When you say the slippage was poor of the 10 initial prototype, what do you mean? 11 A. Less than the tensile strength capability of the 12 existing Arthrex product. 13 Q. So the knot slippage was less than the Tevdek 14 suture? 15 A. Yes. 16 Q. And it was -- knot slippage was such that it was 17 determined that the 100 percent ultra-high molecular 18 weight polyethylene suture prototype wasn't suitable to be 19 developed? 20 A. That's correct. Yes. 21 Q. Okay. Ultra-high molecular weight polyethylene, 22 you said the knot slippage was poor? 23 A. (Witness nods head affirmatively). 24 Q. Ultra-high molecular weight polyethylene, is that 25 a lubricious material?</p> <p>52</p>
<p>1 Q. Okay. And it didn't have nylon or any other 2 material braided with it? 3 A. No. 4 Q. So the initial prototype was a ultra-high 5 molecular weight polyethylene braided suture prototype, if 6 you will? 7 A. Yes. Size 2. 8 Q. Size 2. And was the initial prototype, was it 9 coated? 10 A. I don't remember. 11 Q. Okay. Do you know if the initial prototype went 12 through any other manufacturing process like stretching or 13 heating, twisting? 14 A. I don't recall. 15 Q. Was the initial prototype 100 percent ultra-high 16 molecular weight polyethylene? 17 A. For the fourth time, yes. 18 Q. Okay. And you tested the initial prototype that 19 was 100 percent ultra-high molecular weight polyethylene 20 with Dr. Burkhart and Dr. Chen? 21 A. Dr. Casey Chen, correct. 22 Q. Okay. And the test that you conducted with Dr. 23 Burkhart and Dr. Chen on the ultra-high molecular weight 24 polyethylene was a knot strength test? 25 A. Knot security.</p> <p>51</p>	<p>1 A. Yes. 2 Q. And was the knot slippage of this ultra-high 3 molecular weight polyethylene poor security because of the 4 lubricity of polyethylene? 5 A. Yes. 6 Q. Yes? 7 A. Yes. 8 Q. So then you came up with the idea to braid PET 9 with the ultra-high molecular weight polyethylene to 10 reduce the knot slippage? 11 A. Yes. 12 Q. And when you say knot slippage, we're referring 13 to this knot security test? 14 A. Yes. 15 Q. So are we using the terms knot slippage and knot 16 security interchangeably here? 17 A. You are, yes. 18 Q. In your testimony? 19 A. Yes. 20 Q. So the knot security of the 100 percent 21 ultra-high molecular weight polyethylene was poor, the 22 prototype; right? 23 A. Yes. 24 Q. And your idea was to add the PET and to improve 25 the knot security?</p> <p>53</p>

<p>54</p> <p>1 MR. SOFFEN: Objection; asked and answered.</p> <p>2 You've asked him the same thing multiple times. But</p> <p>3 you can answer.</p> <p>4 A. I've lost count, it's been so many times, but the</p> <p>5 answer again is yes.</p> <p>6 Q. Okay. And Dr. Burkhardt said that was a killer</p> <p>7 idea?</p> <p>8 A. What was a killer idea?</p> <p>9 Q. The killer idea was that your idea of adding</p> <p>10 PED -- PET -- I'm sorry. I'll rephrase that question.</p> <p>11 Did Dr. Burkhardt say that your idea to braid PET</p> <p>12 with the ultra-high molecular weight polyethylene to</p> <p>13 improve knot security was a killer idea?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And then you said you had Pearsalls</p> <p>16 manufacture a prototype that had PET and ultra-high</p> <p>17 molecular weight polyethylene braided?</p> <p>18 A. Yes.</p> <p>19 Q. And you tested that prototype?</p> <p>20 A. Yes.</p> <p>21 Q. And you said that that prototype had good knot</p> <p>22 strength?</p> <p>23 A. Correct.</p> <p>24 Q. And the prototype of PET braided with ultra-high</p> <p>25 molecular weight polyethylene had good knot security?</p>	<p>56</p> <p>1 Q. I'm talking about the --</p> <p>2 A. The second prototype with the PET?</p> <p>3 Q. Correct.</p> <p>4 A. Yes.</p> <p>5 Q. The second prototype that had the coating on it?</p> <p>6 A. Yes.</p> <p>7 Q. And was that part of your initial idea, or was</p> <p>8 that -- because I thought you said your initial idea was</p> <p>9 to add the PET? Was it also to coat it, or was that</p> <p>10 something that came later?</p> <p>11 A. If you're going to market the product, it needs</p> <p>12 the coating on it, sir.</p> <p>13 Q. Okay. But the prototype that was manufactured</p> <p>14 that you asked --</p> <p>15 A. Most likely, it was coated, because it needed to</p> <p>16 be as the final product would be marketed.</p> <p>17 Q. You said most likely. Do you remember or you</p> <p>18 don't remember whether the prototype that had the PET and</p> <p>19 the ultra-high molecular weight polyethylene was coated?</p> <p>20 A. I can't tell you for sure that it was at that</p> <p>21 prototype stage.</p> <p>22 Q. Okay. Was this prototype that you had -- after</p> <p>23 you tested the prototype with PET with ultra-high --</p> <p>24 A. Excuse me. I want to change that.</p> <p>25 Q. Okay.</p>
<p>55</p> <p>1 A. Yes.</p> <p>2 Q. And the prototype of PET and ultra-high molecular</p> <p>3 weight polyethylene braided together also had good tensile</p> <p>4 strength?</p> <p>5 A. Yes.</p> <p>6 Q. And after you tested this second prototype, if</p> <p>7 you will, of the PET braided with ultra-high molecular</p> <p>8 weight polyethylene, was then the decision made to pursue</p> <p>9 trying to commercially develop this idea?</p> <p>10 A. Yes.</p> <p>11 Q. Did you -- when you made -- Who made the decision</p> <p>12 to go forward and try to commercialize this idea?</p> <p>13 A. Myself and Reinhold, surgeons that we</p> <p>14 collaborated with, marketing people. You know, it wasn't</p> <p>15 just myself.</p> <p>16 Q. Okay. Was this prototype that had the PET</p> <p>17 braided with the ultra-high molecular weight polyethylene,</p> <p>18 was it -- did it have a coating on it?</p> <p>19 A. Yes.</p> <p>20 Q. It did?</p> <p>21 A. (Witness nods head affirmatively).</p> <p>22 Q. And what was the coating?</p> <p>23 A. I forget the name. It's like an MED2174s.</p> <p>24 Q. That was on the prototype?</p> <p>25 A. Which prototype are you referring to now?</p>	<p>57</p> <p>1 A. I never got samples of constructions from</p> <p>2 Pearsalls without a coating unless I specifically asked</p> <p>3 for it not to be coated. So there's a very high</p> <p>4 probability that the suture came as -- the second</p> <p>5 prototype -- as coated.</p> <p>6 Q. That was standard for them to coat it, in other</p> <p>7 words?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. So the initial prototype that was</p> <p>10 ultra-high molecular weight polyethylene, did you ask for</p> <p>11 that not to be coated?</p> <p>12 A. No.</p> <p>13 Q. So chances are that that one was coated?</p> <p>14 A. Quite possibly.</p> <p>15 Q. After you tested the prototype of PET and</p> <p>16 ultra-high molecular weight polyethylene braided together,</p> <p>17 did you believe that it would then work as a suture?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Is there anything else you think you</p> <p>20 needed to do in order to determine whether it would work</p> <p>21 as a suture?</p> <p>22 A. Yes.</p> <p>23 Q. What did you need to do?</p> <p>24 A. Biocompatibility toxicity testing, bioburden</p> <p>25 levels, all the design control GNP items that need to be</p>

66

1 decitex?
 2 A. No. No, I can't remember that.
 3 Q. Do you recall evaluating any samples that had
 4 Dyneema 400 denier or higher?
 5 A. No.
 6 Q. Do you think you did or you just don't recall?
 7 A. I received -- I'm sure I received the samples.
 8 What I did with them, I don't recall.
 9 Q. Okay. How long -- how much before this letter do
 10 you think you came up with the idea to use the ultra-high
 11 molecular weight polyethylene with PET blended together?
 12 A. Whatever the Chicago National Sales Meeting was.
 13 The flight just before the start date would be the time
 14 that I came up with the idea. I don't know what that time
 15 is. I just remember the circumstance.
 16 Q. You say Chicago National Sales Meeting?
 17 A. That's correct.
 18 Q. Is that Arthrex National Sales Meeting?
 19 A. Yes.
 20 Q. Was that a meeting with all the Arthrex sales
 21 reps?
 22 A. That's correct.
 23 Q. And it was sometime before the July -- It was the
 24 meeting before the July 10, 19 -- I'm sorry. The meeting
 25 where you came up with the idea was the meeting before the

67

1 July 10th, 1998 date on this letter?
 2 A. Yes.
 3 Q. I show you DePuy Mitek Exhibit 324. Do you
 4 recognize Exhibit 324 as a letter from you to Mr. Hallett?
 5 A. I don't recall the letter, but I recognize my
 6 name and the contact person. But the specific
 7 circumstances of the letter, I don't remember.
 8 Q. Based on your prior testimony, is it then true
 9 that this letter was after you came up with the idea and
 10 after you evaluated the prototype?
 11 A. Yes. After I came up with the idea, yes.
 12 Q. Okay. Was this letter sent before or after you
 13 came up with the -- I'm sorry. Was this November 16th,
 14 1998 letter sent before or after you came up with the --
 15 Sorry. I will rephrase the question.
 16 Was the November 16th, 1998 letter, Exhibit 324,
 17 sent before or after you evaluated the prototype of
 18 ultra-high molecular weight polyethylene braided with PET?
 19 A. I don't recall.
 20 Q. When you had the prototype of PET and ultra-high
 21 molecular weight polyethylene made, do you know if
 22 Pearsalls specifically made that or if they just pulled it
 23 off their line from something else?
 24 A. I'm sure they made it.
 25 Q. They specifically made it?

68

1 A. Yes.
 2 Q. It's not like they had a product that they could
 3 just give to you?
 4 A. No.
 5 Q. In your letter, you say you tested the samples of
 6 Dyneema. Do you see that?
 7 A. Yes.
 8 Q. And then you say, "Can you build a 25 percent
 9 Dyneema/75 percent polyester blend in Size 2 that is very
 10 flexible (like the existing suture or the Ethicon sample)
 11 and send it to me to test"; do you see that?
 12 A. Yes.
 13 Q. Does that Ethicon sample, does that refer to an
 14 Ethibond?
 15 A. Yes.
 16 Q. And you say, "If we get the" -- "If we can get
 17 this blend correct, we will have a terrific advancement in
 18 suture for our soft tissue anchors"; do you see that?
 19 A. Yes.
 20 Q. What did you mean by that?
 21 MR. SOFFEN: Objection; vague. It states what it
 22 states. What's the question?
 23 Q. Do you understand the question?
 24 A. I'm not sure what -- what you're asking.
 25 Q. I would like to know what you mean by in your

69

1 letter when you said, "If we can get this blend correct."
 2 You asked them for a 25 percent Dyneema/75 percent
 3 polyester blend in Size 2 that's very flexible. And then
 4 you said, "If we can get this blend correct, we will have
 5 a terrific advancement."
 6 What did you mean by "If we can get this blend
 7 correct"?
 8 A. The optimization of the two materials. If you
 9 had the knot strength, loop security, and tensile
 10 strength, as well as the tactile feel of the suture all
 11 superior to what was on the market, then it would be a
 12 superior product.
 13 Q. Wait a second. You said optimization of two
 14 materials.
 15 A. (Witness nods head affirmatively).
 16 Q. At this point in time, November 1998, were you
 17 trying to vary the amount and type of the Dyneema and
 18 polyester in the braid in order to get the best
 19 properties?
 20 A. During -- during the -- during that period of
 21 time, yes.
 22 Q. So you were balancing off the properties of each
 23 material to try to get the optimum properties --
 24 A. Tensile strength.
 25 Q. To get the optimum tensile strength?

<p>70</p> <p>1 A. (Witness nods head affirmatively).</p> <p>2 Q. What about knot security?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. So you were varying the amount and type of</p> <p>5 the materials to get the optimum knot security, optimum</p> <p>6 tensile strength?</p> <p>7 A. Yes.</p> <p>8 Q. Any other properties? Knot tiedown?</p> <p>9 A. The slideability of the knot, the tactile feel in</p> <p>10 the surgeon's hands of the material.</p> <p>11 Q. So you were varying type and proportion of the</p> <p>12 materials to optimize all these properties in the product?</p> <p>13 A. Yes.</p> <p>14 Q. Were the product samples that were being made at</p> <p>15 this time in November of 1998, around this time, were they</p> <p>16 being made on a carrier braid machine?</p> <p>17 A. Yes.</p> <p>18 Q. I show you DePuy Mitek Exhibit 325. It's a</p> <p>19 letter dated November 16th, 1998 from Mr. Hallett to you.</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Do you recall receiving this letter?</p> <p>23 A. No.</p> <p>24 Q. It says -- Mr. Hallett says in the letter,</p> <p>25 "Please find enclosed a matrix of information of the</p>	<p>72</p> <p>1 Q. Do you see under the yarns the first one is</p> <p>2 Dyneema?</p> <p>3 A. Yes.</p> <p>4 Q. And is has a DT number. Do you see that?</p> <p>5 A. DT.</p> <p>6 Q. Dt-no. Does that stand for DT number?</p> <p>7 A. Where -- where do you see DT?</p> <p>8 Q. The second column.</p> <p>9 A. At the top as the heading, yes.</p> <p>10 Q. Okay. Are you familiar that Pearsalls uses the</p> <p>11 terminology DT number for samples?</p> <p>12 A. I don't recall what they use.</p> <p>13 Q. You don't recall? Okay.</p> <p>14 Was it the first sample -- Do you see where the</p> <p>15 first one is Dyneema and the second ones are Polys, the</p> <p>16 second through fourth are Poly/Dyneema? Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Was the first sample of yarn here all Dyneema?</p> <p>19 A. Evidently.</p> <p>20 Q. Do you see in the second through the fourth yarns</p> <p>21 were a braided blend of Polyethylene and Dyneema?</p> <p>22 A. Yes.</p> <p>23 Q. Do you see the straight pull column?</p> <p>24 A. Yes.</p> <p>25 Q. I'm sorry. I may have misspoke.</p>
<p>71</p> <p>1 samples that you took with you on your visit to Pearsalls.</p> <p>2 I will endeavor to proceed with the existing trial to</p> <p>3 match the US2 Excel Braid made by Ethicon, in polyester</p> <p>4 construction." Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. Did you pick up the samples from Pearsalls that</p> <p>7 are mentioned in this --</p> <p>8 A. I don't recall.</p> <p>9 Q. Do you recall whether they were actually -- Do</p> <p>10 you recall going over to Pearsalls and having them</p> <p>11 actually make samples while you were there?</p> <p>12 A. Yes.</p> <p>13 Q. And were these samples -- These aren't samples</p> <p>14 they pulled off the line? These are samples where they</p> <p>15 took yarns and braided them according to what you guys</p> <p>16 were considering?</p> <p>17 A. Repeat the question again.</p> <p>18 Q. Sure. I'm just trying to get the sense of</p> <p>19 whether the samples that you picked up while you were at</p> <p>20 Pearsalls that you saw being made, were they -- was it an</p> <p>21 existing product they were picking up off the product</p> <p>22 line, or was this -- you know -- yarns that were selected</p> <p>23 and braided and going through the manufacturing process</p> <p>24 that you particularly picked out?</p> <p>25 A. The latter.</p>	<p>73</p> <p>1 The second through fourth yarns that are listed,</p> <p>2 the Poly/Dyneema, is that -- are they Polyester and</p> <p>3 Dyneema?</p> <p>4 A. Yes.</p> <p>5 Q. Not polyethylene and Dyneema?</p> <p>6 A. It's ultra-high molecular weight polyethylene and</p> <p>7 PET.</p> <p>8 Q. Okay. Do you see the column straight pull?</p> <p>9 A. Yes.</p> <p>10 Q. Do you know what that means?</p> <p>11 A. Testing that they did in their lab with their</p> <p>12 tensile test machine in kilograms.</p> <p>13 Q. Is that with a knot or without a knot?</p> <p>14 A. That's without a knot.</p> <p>15 Q. Okay. And do you see how the Dyneema one was</p> <p>16 23.12 kilograms?</p> <p>17 A. Yes.</p> <p>18 Q. And Poly/Dyneemas were on the order of 34 to 36</p> <p>19 kilograms?</p> <p>20 A. Yes.</p> <p>21 Q. Do you know why the difference in strength</p> <p>22 between the Dyneema one and the other ones?</p> <p>23 A. You can't tell by looking at this report why</p> <p>24 there's a difference.</p> <p>25 Q. And you don't remember?</p>

<p>1 Q. Okay. I show you DePuy Mitek Exhibit 164. Do 2 you recognize Exhibit 164 as a letter from Mr. Hallett to 3 you? 4 A. Yes. 5 Q. And did you receive Exhibit 164 on October 19th, 6 2000? 7 A. Evidently so. 8 Q. It says the subject is Polyester-Dyneema Braid. 9 Do you see that? 10 A. Yes. 11 Q. And then it says, "Dear Don: Please find 12 enclosed four DT trials samples for your inspection. 13 These have been made using Polyester/Dyneema mixed either 14 in the core -- I'm sorry -- mixed either in the cover or 15 straight core to match US2. I have set up below a matrix 16 of how each was made and the results for your 17 information." Do you see that? 18 A. Yes. 19 Q. And the first sample is the DT PA23 sample. Do 20 you see that? 21 A. Yes. 22 Q. And if you go down to the cover, it was 16 23 carriers in use each with one end of 138 d'tex Polyester 24 per carrier. Do you see that? 25 A. Mmm-hmm (affirmative).</p>	78	<p>1 use, 16 carriers with one end of 113 polyester per 2 carrier. Do you see that? 3 A. Yes. 4 Q. So the DT PA27 had a polyester braided cover; 5 right? 6 A. Yes. 7 Q. Okay. Now if you look at the knot pull strength 8 of each, of the DT PA23, which was a polyester cover, had 9 a 10.35 at the finish stage of knot pull? 10 A. Yes. 11 Q. And the DT PA25 had a knot pull at the center 12 stage of 11.95? 13 A. Yes. 14 Q. Do you know what the finish stage is? 15 A. Yes. 16 Q. What is the finish stage? 17 A. After coating. 18 Q. Okay. And the DT PA26 had a knot pull of 12.87; 19 do you see that? 20 A. Yes. 21 Q. And the DT PA27 had a knot pull at finish of 22 8.04. Do you see that? 23 A. Yes. 24 Q. So if you look back and look at the numbers, the 25 first one, the DT PA23 was the polyester cover braid, and</p>	80
<p>1 Q. So the first sample of DT PA23 had a cover that 2 was all polyester; right? 3 A. Yes. 4 Q. And is this letter part of the development of 5 FiberWire? It was sent to you in connection with the 6 development of FiberWire? 7 A. Yes. 8 Q. If you turn over to the next page, the second 9 sample is DT PA25. And if you look at the cover 10 construction, it was 16 carriers in use, 8 carriers with 11 one end of 113 polyester, 8 carriers with one end of 110 12 Dyneema. Do you see that? 13 A. Yes. 14 Q. So the PA25 had a cover that was a 15 Polyester/Dyneema blend? 16 A. Correct. 17 Q. The DT PA26, the construction of that cover was 18 16 carriers in use, 8 carriers with one end of 113 19 polyester, 8 carriers with one end of 110 Dyneema. Do you 20 see that? 21 A. Yes. 22 Q. So the DT PA26 had a Polyester/Dyneema braid 23 construction in the cover? 24 A. Correct. 25 Q. And the DT PA27 had a cover of 16 carriers in</p>	79	<p>1 its knot strength at finish was less than the DT PA25 and 2 DT PA26; correct? 3 A. Yes. 4 Q. And DT PA27 was also a polyester cover, and its 5 knot strength at finish stage was less than that of DT 6 PA25 and 26; right? 7 A. Yes. 8 Q. Do you know why the DT PA23 and PA 27 samples had 9 lower knot pull strength at the finish stage than DT PA25 10 and DT PA26? 11 A. Because there was no Dyneema in the jacket or 12 cover. 13 Q. And you say that the finish stage was after 14 coating, so all these products had the -- I'm sorry -- so 15 you said the finish stage was after coating, so the DT 16 PA23, 25, 26, and 27 all had coating on it? 17 A. Yes. 18 Q. They had the same coating? 19 A. Yes. 20 Q. They went through the same coating processes? 21 A. Yes. 22 Q. If you look at the d'tex of the Dyneema yarn that 23 was used in these prototypes, it was -- in the cover, the 24 DT PA25 had 110 Dyneema, and the DT PA26 also had 110 25 Dyneema in the cover? Do you see that?</p>	81

<p>1 Q. You're sure you did?</p> <p>2 A. Yes.</p> <p>3 Q. And what did you review it for?</p> <p>4 A. Accuracy, to be sure it covered as much of a</p> <p>5 claim area as possible.</p> <p>6 Q. Okay. Do you recall having any discussions with</p> <p>7 an attorney that this patent -- patent Exhibit 423 was not</p> <p>8 accurate?</p> <p>9 A. I don't recall that, no.</p> <p>10 Q. Do you recall asking an attorney to change</p> <p>11 anything in Exhibit 423 and having them say no?</p> <p>12 A. I don't know. I don't recall.</p> <p>13 Q. And do you see how on the front of Exhibit 423,</p> <p>14 if you look on the first page, it says the Agent, Attorney</p> <p>15 or Firm, do you see where it says Dickstein, Shapiro,</p> <p>16 Morin & Oshinsky, LLP; do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Do you recall working with attorneys from</p> <p>19 Dickstein, Shapiro, Morin & Oshinsky in preparing this</p> <p>20 application?</p> <p>21 A. Yes.</p> <p>22 Q. Do you recall working with Mr. Soffen in</p> <p>23 preparing this patent application that became the '423</p> <p>24 patent?</p> <p>25 A. Yes.</p>	<p>102</p> <p>1 stronger than ordinary surgical suture, does not have</p> <p>2 acceptable knot tiedown characteristics for use in</p> <p>3 surgical applications." Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. Do you agree with that?</p> <p>6 A. Yes.</p> <p>7 Q. Do you see the reference to knot tiedown?</p> <p>8 A. Yes.</p> <p>9 Q. Is that reference to knot tiedown what we</p> <p>10 referred to this morning as knot tiedown as you described</p> <p>11 it?</p> <p>12 A. It's one of the items we referred to, yes.</p> <p>13 Q. And how you defined it this morning, is -- are</p> <p>14 you using that same definition here?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. If you go on the front page of this</p> <p>17 document, it notes Patent Documents -- U.S. Patent</p> <p>18 Documents References Cited; do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And there's a section of Foreign Patent Documents</p> <p>21 and Other Publications. Do you see that?</p> <p>22 A. Mmm-hmm (affirmative). Yes.</p> <p>23 Q. Do you recall whether you asked for any fishing</p> <p>24 line products to be disclosed to the patent office that</p> <p>25 used ultra-high molecular weight polyethylene?</p> <p>104</p>
<p>103</p> <p>1 Q. Is Mr. Soffen generally the person you've worked</p> <p>2 with in preparing patent -- patent applications?</p> <p>3 A. He's one of them, yes.</p> <p>4 Q. Okay. And how about Mr. McGee?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. Do you have an understanding that in</p> <p>7 providing a description of your invention, that the</p> <p>8 invention should be sufficiently described so that someone</p> <p>9 skilled in the art could make it?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. If I could turn to paragraph -- the text</p> <p>12 beginning on Page ARM 286, the second paragraph, the</p> <p>13 description of the related art. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. It says, "Suture strength is an important</p> <p>16 consideration in surgical suture material." Do you agree</p> <p>17 with that?</p> <p>18 A. Yes.</p> <p>19 Q. It says, "One of the strongest materials</p> <p>20 currently formed into elongated strands is an ultra-high</p> <p>21 molecular long chain weight polyethylene typically used</p> <p>22 for fishing lines and the like which is sold under the</p> <p>23 trade names Dyneema or Spectra." Do you agree with that?</p> <p>24 A. Yes.</p> <p>25 Q. It says, "However, this material, while much</p>	<p>105</p> <p>1 A. Don't recall.</p> <p>2 Q. Go to the Detailed Description of the Preferred</p> <p>3 Embodiments. Do you see that? It begins on Column 2.</p> <p>4 A. Yes.</p> <p>5 Q. It says, "Referring to FIG. 1, a scanning</p> <p>6 electron micrograph of a length of suture 2 according to</p> <p>7 the present invention is shown."</p> <p>8 A. Excuse me. I'd like to interrupt you --</p> <p>9 Q. Sure.</p> <p>10 A. -- on one of your comments. I want to be sure I</p> <p>11 get that correct. The -- When you said whether I</p> <p>12 specifically asked for a fishing line or fishing line</p> <p>13 patents to be looked at --</p> <p>14 Q. I didn't say patent. I said products.</p> <p>15 A. Products? The key word would have been put in</p> <p>16 for the materials used, and if those then had a hit, if</p> <p>17 you will, with the fishing line, then that patent would</p> <p>18 have come up.</p> <p>19 Q. Right. But I'm just talking about products</p> <p>20 like -- that were on the market like fishing line</p> <p>21 products.</p> <p>22 A. No. No. That was --</p> <p>23 Q. Like the one Pearsalls made.</p> <p>24 A. No, we didn't look at Spider Wire or other</p> <p>25 fishing lines.</p>

BROOKSTEIN DECLARATION

EXHIBIT 4



US006716234B2

(12) **United States Patent**
Grafton et al.

(10) Patent No.: **US 6,716,234 B2**
(45) Date of Patent: **Apr. 6, 2004**

(54) **HIGH STRENGTH SUTURE MATERIAL**

(75) Inventors: **R. Donald Grafton, Naples, FL (US);
D. Lawson Lyon, Exeter (GB); Brian
Hallet, Taunton (GB)**

(73) Assignee: **Arthrex, Inc., Naples, FL (US)**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

(21) Appl. No.: **09/950,598**

(22) Filed: **Sep. 13, 2001**

(65) **Prior Publication Data**

US 2003/0050666 A1 Mar. 13, 2003

(51) Int. Cl.⁷ **A61L 17/04**

(52) U.S. Cl. **606/228**

(58) Field of Search **606/228**

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,942,532 A	3/1976	Hunter et al.	
4,047,533 A *	9/1977	Perciaccante et al.	606/230
4,344,908 A	8/1982	Smith et al.	264/203
4,411,854 A	10/1983	Maurer et al.	264/205
4,422,993 A	12/1983	Smith et al.	264/210.8
4,430,383 A	2/1984	Smith et al.	428/364
4,436,689 A	3/1984	Smith et al.	264/204
4,668,717 A	5/1987	Lemstra et al.	523/322
5,019,093 A *	5/1991	Kaplan et al.	606/228
5,067,538 A	11/1991	Neison et al.	152/451

5,234,764 A	8/1993	Nelson et al.	428/364
5,261,886 A *	11/1993	Chesterfield et al.	606/228
5,318,575 A	6/1994	Chesterfield et al.	606/151
5,383,925 A *	1/1995	Schmitt	623/1.53
5,403,659 A	4/1995	Nelson et al.	428/364
5,540,703 A	7/1996	Barker, Jr. et al.	
5,630,976 A	5/1997	Nelson et al.	264/210.8
5,720,765 A *	2/1998	Thal	606/232
6,045,571 A *	4/2000	Hill et al.	606/228
6,063,105 A *	5/2000	Totakura	606/228

FOREIGN PATENT DOCUMENTS

EP 0561108 A2 9/1993

OTHER PUBLICATIONS

"SecureStrand™ Cable System," Surgical Dynamics, Inc. 1999.

* cited by examiner

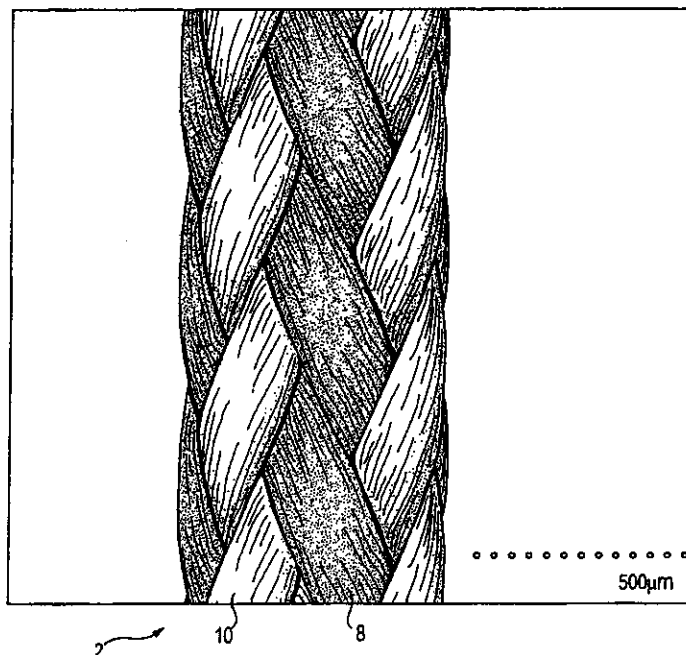
Primary Examiner—David O. Reip

(74) Attorney, Agent, or Firm—Dickstein Shapiro Morin & Oshinsky, LLP

(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets

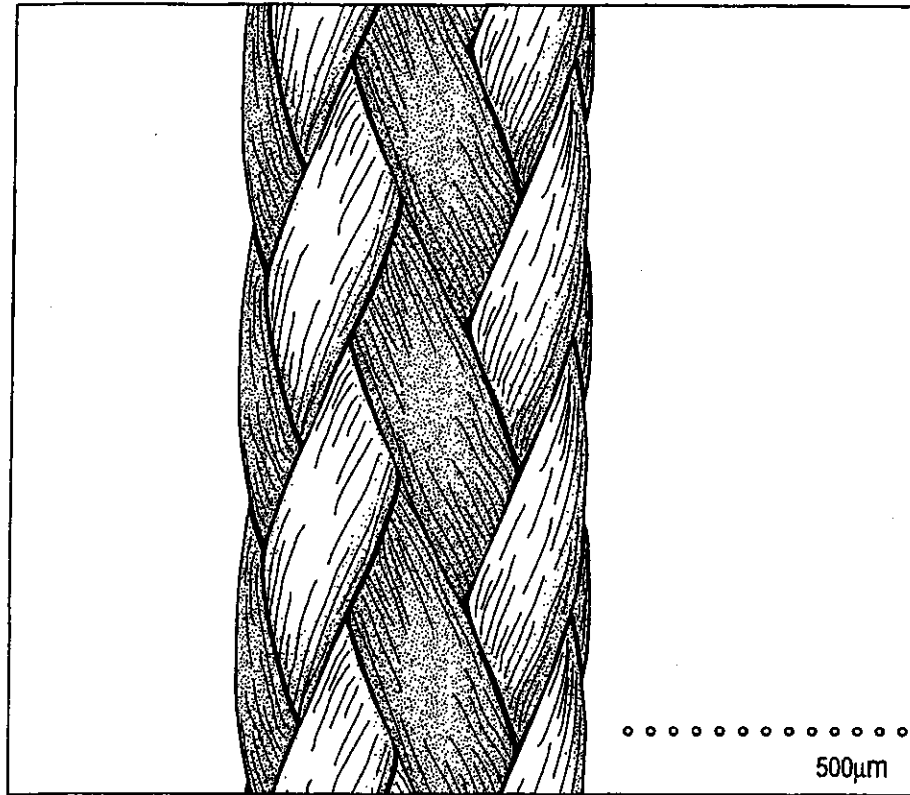


U.S. Patent

Apr. 6, 2004

Sheet 1 of 2

US 6,716,234 B2



2

FIG. 1

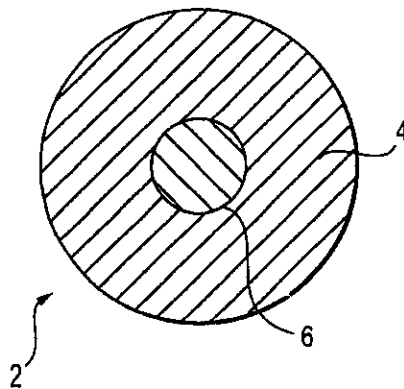


FIG. 2

U.S. Patent

Apr. 6, 2004

Sheet 2 of 2

US 6,716,234 B2

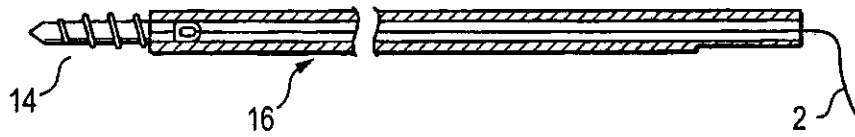


FIG. 3

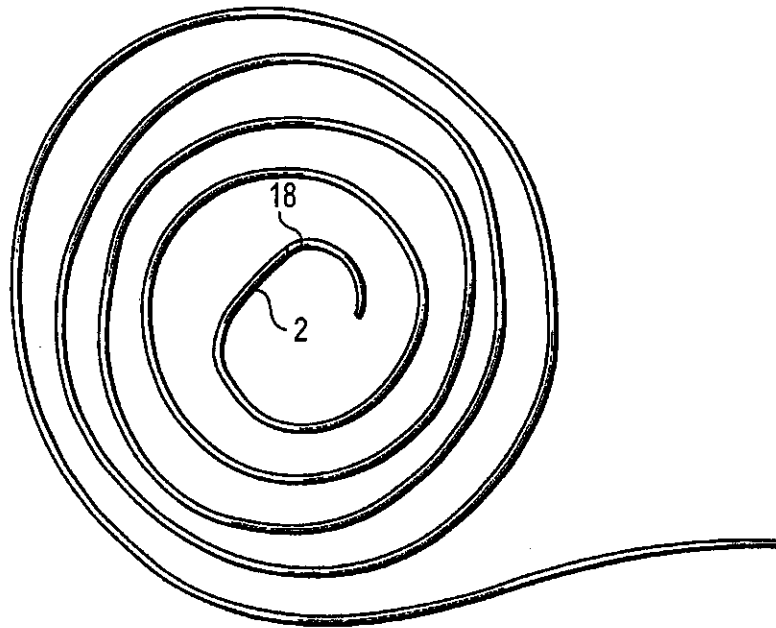


FIG. 4A

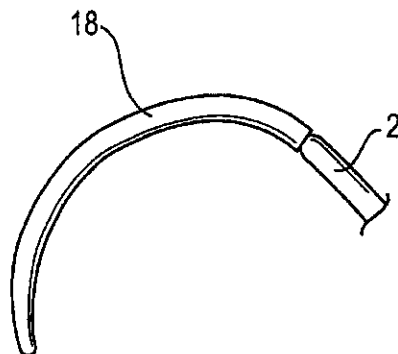


FIG. 4B

US 6,716,234 B2

1

HIGH STRENGTH SUTURE MATERIAL**BACKGROUND OF THE INVENTION****1. Field of the Invention**

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. 1 is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. 2 is a schematic cross section of a length of suture according to the present invention.

FIG. 3 is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. 4A and 4B show the suture of the present invention attached to a half round, tapered needle.

2

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, a scanning electron micrograph of a length of suture 2 according to the present invention is shown. Suture 2 is made up of a cover 4 and a core 6 surrounded by the cover. See FIG. 2. Strands of ultrahigh molecular weight polyethylene (UHMWPE) 8, sold under the tradename Dyneema or Spectra, and strands of polyester 10 are braided together to form the cover 4. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

EXAMPLE 1**USP Size 5 (EP size 7)**

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

EXAMPLE 2**USP Size 2**

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

US 6,716,234 B2

3

In one method of using the suture of the present invention, the suture 2 is attached to a suture anchor 14 as shown in FIG. 3 (prepackaged sterile with an inserter 16), or is attached to a half round, tapered needle 18 as shown in FIGS. 4A and 4B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and
a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim 1, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim 1, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim 1, wherein the core comprises about 30% of the filament.

4

5. The suture filament of claim 1, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim 1, further comprising a coating disposed on the cover.

7. The suture filament of claim 1, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *

BROOKSTEIN DECLARATION EXHIBIT 5

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

1 IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
2 IN AND FOR THE NEW CASTLE COUNTY

3 DEPUY MITEK, INC., a Massachusetts)
4 Corporation,)
5 Plaintiff,)
6 v.)
7 ARTHREX, INC., a Delaware)
8 Corporation,)
9 Defendant.)

Civil Action
No. 04-12457 PBS

HIGHLY
CONFIDENTIAL

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
- UNITED-KINGDOM

on
11th January 2006

Condensed Copy

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p style="text-align: right;">46</p> <p>1 MR. BONELLA: What do you mean by that?</p> <p>2 MR. TAMBURIO: -- but I take you at your</p> <p>3 word that this is the 30(b)(6) portion of</p> <p>4 the deposition, and again, to the extent that</p> <p>5 this testimony you are requesting right now is</p> <p>6 duplicative of testimony that was already given</p> <p>7 by Pearsalls in the past for this topic, topics</p> <p>8 number 4, 5, 6 and 7 of the original notice,</p> <p>9 Arthrex and Pearsalls are objecting to the</p> <p>10 duplicative testimony requested.</p> <p>11 MR. BONELLA: Let's just move on. We will</p> <p>12 resolve it later. Exhibit 280. Do you</p> <p>13 recognize that, Mr. Hallett?</p> <p>14 A I recognize it as it is.</p> <p>15 Q What is Exhibit 280?</p> <p>16 A It is a result of a batch of US2</p> <p>17 FiberWire.</p> <p>18 Q Exhibit 280 is batch testing results?</p> <p>19 A Hmm hmm.</p> <p>20 Q The tests describe in Exhibit 280 are,</p> <p>21 those tests that are run in the standard, ordinary</p> <p>22 business of Pearsalls?</p> <p>23 A Correct.</p> <p>24 Q Do you see the test at the intermediate</p> <p>25 stage?</p>	<p style="text-align: right;">48</p> <p>1 that have undergone the dyeing and scouring</p> <p>2 processes and all processes before that?</p> <p>3 A Yes.</p> <p>4 Q You have labeled Exhibit 280, "Stretch</p> <p>5 stage"?</p> <p>6 A Hmm hmm.</p> <p>7 Q On Exhibit 279; correct?</p> <p>8 A Yes.</p> <p>9 Q The samples -- I am sorry, the stretch</p> <p>10 stage testing that is in Exhibit 280, does that</p> <p>11 I undergo the stretching in all processes before that?</p> <p>12 A Yes.</p> <p>13 Q The samples that have gone -- that are</p> <p>14 stretch-tested in Exhibit 280 -- I am sorry, I will</p> <p>15 rephrase the question. The samples that have been</p> <p>16 stretch-tested as reflected in Exhibit 280 have not</p> <p>17 been coated. Is that correct?</p> <p>18 A No.</p> <p>19 Q "No", it is not correct?</p> <p>20 A No. It is not correct.</p> <p>21 Q The samples that have been stretch test --</p> <p>22 I am sorry, the samples that are tested at the</p> <p>23 stretch stage have undergone the stretching and</p> <p>24 coating processes?</p> <p>25 A Yes.</p>
<p style="text-align: right;">47</p> <p>1 A Yes.</p> <p>2 Q Can you label in the manufacturing</p> <p>3 flowchart where that test was done? Can you label</p> <p>4 that as the intermediate stage? Okay. So, where you</p> <p>5 have labeled Exhibit 280 interim/stage on Exhibit</p> <p>6 279 reflects the intermediate stage testing done in</p> <p>7 Exhibit 280?</p> <p>8 A Yes.</p> <p>9 Q If you could identify -- there is</p> <p>10 a measure stage testing in Exhibit 280; correct?</p> <p>11 A Hmm hmm.</p> <p>12 Q Could you label on Exhibit 279 where the</p> <p>13 measure stage testing is?</p> <p>14 A So, do you want me to put the --</p> <p>15 Q If you could just put, "Measure stage"?</p> <p>16 "Exhibit 280 measure stage", and there is also the</p> <p>17 stretch stage. Would you label where that is in</p> <p>18 Exhibit 279? And there is also the dye stage</p> <p>19 testing. Could you label where that is in Exhibit</p> <p>20 279? Exhibit -- you have labeled in Exhibit 279,</p> <p>21 "Exhibit 280 dye stage", and that refers to the dye</p> <p>22 stage testing in Exhibit 280?</p> <p>23 A Yes.</p> <p>24 Q The dye testing that is done in Exhibit</p> <p>25 280, is that all -- is that of samples of FiberWire</p>	<p style="text-align: right;">49</p> <p>1 Q Are you sure about that?</p> <p>2 A Repeat the question again.</p> <p>3 Q Sure. The stretch testing, samples that</p> <p>4 are tested at the stretch stage as in Exhibit 280,</p> <p>5 have they undergone the stretching and coating</p> <p>6 processes that are reflected in Exhibit 279?</p> <p>7 MR. TAMBURIO: Asked and answered,</p> <p>8 objection.</p> <p>9 MR. BONELLA: Mr. Tamburo is going to</p> <p>10 object to questions, but unless he instructs</p> <p>11 you not to answer you have to answer the</p> <p>12 question.</p> <p>13 A Yes.</p> <p>14 Q The intermediate stage testing, have those</p> <p>15 samples been stretched and coated?</p> <p>16 A Yes.</p> <p>17 Q What is the difference between the</p> <p>18 intermediate stage testing and the stretched stage</p> <p>19 testing samples?</p> <p>20 A They are tested before they are actually</p> <p>21 coated.</p> <p>22 Q Which are tested before they are coated?</p> <p>23 A The yarn. The braid.</p> <p>24 Q The samples that are tested during the</p> <p>25 stretched stage, have they been stretched?</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p style="text-align: right;">82</p> <p>1 process?</p> <p>2 A It is not a stretch as such, it is just --</p> <p>3 we call it stretching because it is run through some</p> <p>4 pads just to align all of the filaments in the yarn.</p> <p>5 Q What do you mean by that?</p> <p>6 A Well, it just pulls it straight.</p> <p>7 Q Pulls it straight? The material isn't</p> <p>8 stretched?</p> <p>9 A Very minute.</p> <p>10 Q Very minute. And then the coating that we</p> <p>11 see here, it goes through a bath or a dip of glue</p> <p>12 seal and then the FiberWire is put through?</p> <p>13 A It is a bath. We use it as a bath.</p> <p>14 Q "Bath". Okay. And what is the rate at</p> <p>15 which the yarn passes through the bath?</p> <p>16 A 20 metres per minute.</p> <p>17 Q Is that the same for all FiberWire?</p> <p>18 A Yes.</p> <p>19 Q And then this machine here dries it?</p> <p>20 A There are four (inaudible) which actually</p> <p>21 dry it as it is going through.</p> <p>22 Q And then it is wound up to a bobbin at the</p> <p>23 other end?</p> <p>24 A To that bobbin on the other end.</p> <p>25 Q Now, as the FiberWire yarn itself goes</p>	<p style="text-align: right;">84</p> <p>1 FiberWire undergoes this stretching process here;</p> <p>2 right?</p> <p>3 A Correct.</p> <p>4 Q Now, when the yarn comes in and goes</p> <p>5 through the stretching process, does any material</p> <p>6 change take place during the stretching process?</p> <p>7 MR. TAMBURO: Same objection.</p> <p>8 A No.</p> <p>9 MR. BONELLA: Are there any changes in the</p> <p>10 strength characteristics of the yarn after</p> <p>11 the --</p> <p>12 A Yes.</p> <p>13 Q Let me rephrase the question. During the</p> <p>14 stretching process, is there any change to the</p> <p>15 stretch properties?</p> <p>16 MR. TAMBURO: Same objection.</p> <p>17 A Yes.</p> <p>18 MR. BONELLA: In what way?</p> <p>19 A It gets stronger.</p> <p>20 Q The yarn is stronger after the stretching</p> <p>21 process?</p> <p>22 A Yes.</p> <p>23 Q When you say, "Stronger", what type of</p> <p>24 strength are you talking about?</p> <p>25 A The long strength of it goes up.</p>
<p style="text-align: right;">83</p> <p>1 through the stretching and then the coating, does</p> <p>2 the process change in anything itself?</p> <p>3 MR. TAMBURO: Object to the form of the</p> <p>4 question, calls for a legal conclusion.</p> <p>5 A Do I have to answer that?</p> <p>6 MR. TAMBURO: You can answer, yes.</p> <p>7 A It actually makes it stronger in the</p> <p>8 lubrication of the actual suture when it is being</p> <p>9 used afterwards.</p> <p>10 MR. BONELLA: The material that is</p> <p>11 braided, the yarn, both the PET and the</p> <p>12 polyester, does any material change happen to</p> <p>13 them?</p> <p>14 MR. TAMBURO: Object to the form of that</p> <p>15 question.</p> <p>16 MR. BONELLA: So, no material change</p> <p>17 happens to the polyester and ultra high</p> <p>18 molecular weight polythethylene as the</p> <p>19 FiberWire goes through the stretching and</p> <p>20 coating processes?</p> <p>21 MR. TAMBURO: Same objection.</p> <p>22 A No.</p> <p>23 MR. BONELLA: To the wire?</p> <p>24 A Can you repeat the question?</p> <p>25 Q Sure. The FiberWire yarn for all sizes of</p>	<p style="text-align: right;">85</p> <p>1 Q The long strength of it goes up?</p> <p>2 A Yes.</p> <p>3 Q How about the tensile strength?</p> <p>4 A Yes.</p> <p>5 Q Any other strengths that go up or down</p> <p>6 before or after the stretching process?</p> <p>7 MR. TAMBURO: Objection, outside the scope</p> <p>8 of this 30(b)(6) notice. The questions were</p> <p>9 asked and answered already previously in the</p> <p>10 United States during the previous 30(b)(6)</p> <p>11 deposition, so I object to this line of</p> <p>12 questioning.</p> <p>13 A The extension goes down.</p> <p>14 MR. BONELLA: The what does?</p> <p>15 A The extension.</p> <p>16 Q What do you mean by extension?</p> <p>17 A It doesn't need so much -- more stretching</p> <p>18 in the braid.</p> <p>19 Q No more stretching in the braid. Is that</p> <p>20 something that happens after?</p> <p>21 A Yes.</p> <p>22 Q What does that alter in the property?</p> <p>23 A Extension.</p> <p>24 Q Is that the same as elongation?</p> <p>25 A Yes.</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p style="text-align: right;">86</p> <p>1 Q Does the modulus for the material change</p> <p>2 during the stretching process?</p> <p>3 MR. TAMBURRO: Same objection.</p> <p>4 A I don't know.</p> <p>5 MR. BONELLA: Is there testing done on</p> <p>6 that?</p> <p>7 A No.</p> <p>8 Q Do you know what I mean by, "Modulus"?</p> <p>9 A Whether it alters.</p> <p>10 Q Right.</p> <p>11 A Yes.</p> <p>12 Q Do you know what the modulus is referring</p> <p>13 to?</p> <p>14 A I should imagine the make-up of the ultra</p> <p>15 high ...</p> <p>16 Q The modulus I am referring to would be the</p> <p>17 slope of the stress strength, the stressed strain</p> <p>18 curve.</p> <p>19 A The curve of the --</p> <p>20 Q No. If you did a test, a stress strain</p> <p>21 plot for FiberWire before and after the stretching</p> <p>22 process, does the slope of that curve change at all</p> <p>23 with respect to the FiberWire?</p> <p>24 MR. TAMBURRO: Objection, calls for</p> <p>25 speculation, asked and answered.</p>	<p style="text-align: right;">88</p> <p>1 A It helps to penetrate the new seal coating</p> <p>2 within the braid structure. It dilutes the coating</p> <p>3 as well as attaching itself.</p> <p>4 Q Where in the processing is the Xylene</p> <p>5 added to the machine?</p> <p>6 A In the tank.</p> <p>7 Q So, is the Zylene mixed together in the</p> <p>8 tank for the FiberWire to be put through it?</p> <p>9 A That's correct.</p> <p>10 Q Any material properties change to the</p> <p>11 FibreWire yarn itself during the stretching and the</p> <p>12 coating process?</p> <p>13 MR. TAMBURRO: Object to the form of the</p> <p>14 question. Calls for an expert conclusion, and</p> <p>15 outside of the scope of this 30(b)(6) notice.</p> <p>16 A Change?</p> <p>17 MR. BONELLA: Any material process altered</p> <p>18 by the ultra high molecular weight</p> <p>19 polythethylene or the polyester?</p> <p>20 MR. TAMBURRO: Object to the form of the</p> <p>21 question, calls for a legal conclusion and</p> <p>22 speculation and it has already been covered in</p> <p>23 a previous 30(b)(6) deposition.</p> <p>24 A I don't know.</p> <p>25 Q You don't know?</p>
<p style="text-align: right;">87</p> <p>1 A I don't know.</p> <p>2 MR. BONELLA: You don't know whether it</p> <p>3 does?</p> <p>4 A Correct.</p> <p>5 Q Now, in the dyeing process, what pressure</p> <p>6 is that done at? I am sorry, the coating process.</p> <p>7 The coating process. What temperature is that done</p> <p>8 at?</p> <p>9 A I am not. 27 degrees.</p> <p>10 Q Celsius?</p> <p>11 A Yes.</p> <p>12 Q Pressure? What is the pressure?</p> <p>13 Atmospheric?</p> <p>14 A I don't know.</p> <p>15 Q There is no pressure put into this</p> <p>16 machine?</p> <p>17 A No.</p> <p>18 Q Is there a solvent used in this coating?</p> <p>19 A Yes.</p> <p>20 Q What is that?</p> <p>21 A Xylene (Phonetic).</p> <p>22 Q Any other material used in the coating</p> <p>23 process?</p> <p>24 A No.</p> <p>25 Q What is the purpose of the Xylene?</p>	<p style="text-align: right;">89</p> <p>1 A No.</p> <p>2 Q Why don't you know?</p> <p>3 A I am not sure of the question you are</p> <p>4 asking.</p> <p>5 Q For example, the ultra high -- the</p> <p>6 FiberWire braid that goes, that comes out of the</p> <p>7 stretch, then goes through the process, after it has</p> <p>8 been coated, does anything change with respect to</p> <p>9 the FiberWire ultra high molecular weight</p> <p>10 polythethylene, or does anything change with respect</p> <p>11 to the polyester?</p> <p>12 MR. TAMBURRO: Object to the form of the</p> <p>13 question. If you want to narrow it down, it has</p> <p>14 big properties, but that is a very broad</p> <p>15 question, the way it has been worded.</p> <p>16 A The only thing I can say is that the</p> <p>17 changes are not altered. That is the whole idea of</p> <p>18 putting the coating on, and I hope it makes it more</p> <p>19 easier for when the surgeon actually ties the knot.</p> <p>20 Q Is there anything else that changes?</p> <p>21 A Not that I am aware of.</p> <p>22 Q Okay. Now, does the tensile strength</p> <p>23 change before or after the coating?</p> <p>24 MR. TAMBURRO: Objection. Same objections</p> <p>25 a previously noted.</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p>94</p> <p>1 number 2 bobbin was before the coating, the 2 stretching, and the bobbin after the coating 3 stretching, is that -- 4 A It does help. 5 Q It does help? Is there any other -- is 6 there any carrier bobbins during this process? 7 A No. 8 Q There is only two bobbins, the beginning 9 and the end? 10 A Yes. 11 Q What part of the yarn is stretched? 12 A There is no stretch. I have told you 13 that. The only stretch taking place is through the 14 pad. 15 Q Through the pad? 16 A And it is very minute. It is taking off 17 the excess coating, and aligning all the film within 18 that braid. 19 Q Is the speed at which the bobbin in moves 20 itself the same as the output bobbin? 21 A Or -- it doesn't matter. I think it 22 doesn't matter. They are bound to vary because that 23 one is taking on more than that one over there. 24 Q The stretching process that you are 25 referring to is the pads, are you saying that it</p>	<p>96</p> <p>1 question, and it calls for expert testimony. 2 A I don't know. 3 MR. BONELLA: You don't know? Right. Do 4 you know the specification parameters for what 5 tension that the yarn is under during the 6 stretching process? 7 MR. TAMBURRO: Object to the form of the 8 question. That testimony -- mischaracterizing 9 the prior testimony. 10 MR. BONELLA: I am sorry. Is the 11 FiberWire under tension during the stretching 12 process? 13 A Yes. 14 Q Where is the specification for that? 15 A It is written down in the process. 16 Q In the process. Okay. We need to go off 17 the record. 18 (11.48 am) 19 OFF THE RECORD 20 (11.53 am) 21 MR. BONELLA: Mr. Hallett, when you 22 referred to a pad, do you mean a rubber roller? 23 A Rubber pads. 24 Q Rubber pads. Not a roller? 25 A No.</p>
<p>95</p> <p>1 goes to a line yarn? 2 A It takes off any excess coating. 3 Q After that? 4 A Yes. 5 Q Now, the oven process that we have here, 6 I think you referred to it as drying and the curing? 7 A That's correct. 8 Q Is the drying process here a technical 9 curing process, or is it just drying the yarn? 10 MR. TAMBURRO: Object to the form of the 11 question. 12 A It does. 13 MR. BONELLA: What do you mean by that? 14 A Well, it is actually acting as a -- it 15 dries out the coating, it burns off any excess 16 chemicals as it comes through the bath, and it acts 17 as actually purifies the new coating. 18 Q Purifies it? What do you mean by that? 19 A Without speculation, I would just imagine 20 it is -- fills in any gaps and makes sure it is 21 completely covered. 22 Q Is there material change that takes place 23 during the -- is there any change that takes place 24 on the coating during the drying process? 25 MR. TAMBURRO: Objection to the form of the</p>	<p>97</p> <p>1 Q Can you describe the pads? 2 A I can show you one, if you want. 3 Q Can you show me one? These are the rubber 4 pads? (Pause) 5 These are rubber pads. This is 6 a white one and a brown one? 7 A Yes. 8 Q Can you describe how they work? 9 A The braid is sandwiched in between, so 10 these are put in between two brackets. The brackets 11 are screwed down as tight as possible allowing just 12 the minimum of braid to come through. So, 13 therefore, that does allow a little bit of stretch 14 and it takes off the excess Nusil. So, what we have 15 is a brown pad and a white pad and the FiberWire. 16 goes between the two. 17 Q The two pads remove excess coatings? 18 A That's correct. 19 Q They subtly stretch the yarn? 20 A Under some tension, yes. 21 Q Do you know what that tension is? 22 A Yes. 23 Q Is it measurable? 24 MR. TAMBURRO: Object to the form. 25 A No.</p>

25 (Pages 94 to 97)

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p style="text-align: right;">118</p> <p>1 A Yes.</p> <p>2 Q It was just the --</p> <p>3 A That is done for the machine when it is</p> <p>4 set up for -- before they go in with a full run, to</p> <p>5 make sure the parameters are set up correctly within</p> <p>6 the machine.</p> <p>7 Q It would be fair to say that -- wouldn't</p> <p>8 you have the input bobbin material, it goes through</p> <p>9 the stretching, coating, drying process, comes up on</p> <p>10 the take-up roller and a portion of that is sampled</p> <p>11 from over here, tested, and you can figure out what</p> <p>12 the knot pull, straight pull are, and if they are</p> <p>13 acceptable, then continue on with the process?</p> <p>14 A That's correct.</p> <p>15 Q Then the intermediate sample is taken at</p> <p>16 some point?</p> <p>17 A That is done afterwards.</p> <p>18 Q After the whole process is completed?</p> <p>19 A Yes.</p> <p>20 Q "Come over here, test the..."</p> <p>21 A A percentage of that batch is tested.</p> <p>22 Q Is tested, and that is the representative</p> <p>23 of the batch?</p> <p>24 A Yes.</p> <p>25 Q Then we have the measure stage testing?</p>	<p style="text-align: right;">120</p> <p>1 testing have they all undergone two cycles of</p> <p>2 the coating?</p> <p>3 A They would have done, yes.</p> <p>4 MR. BONELLA: If we could move to the</p> <p>5 final stage that would be great.</p> <p>6 (12.40 pm)</p> <p>7 OFF THE RECORD</p> <p>8 (12.42 pm)</p> <p>9 MR. BONELLA: Are we in the room where the</p> <p>10 time inspection and measuring process is</p> <p>11 performed?</p> <p>12 A That's correct, yes.</p> <p>13 Q What is the time inspection and measuring</p> <p>14 process performed in this room?</p> <p>15 A It is wound to a final bobbin which is</p> <p>16 actually then sent out to the customer.</p> <p>17 Q Any tensioning that is applied to the yarn</p> <p>18 during this process?</p> <p>19 A Only through a clock which is actually</p> <p>20 giving the length, and the tension is given by the</p> <p>21 girls who actually control the speed of the bobbin</p> <p>22 which is taken off.</p> <p>23 Q It is minimal tension?</p> <p>24 A Very minimal.</p> <p>25 Q Okay, and what is performed during this</p>
<p style="text-align: right;">119</p> <p>1 A Yes.</p> <p>2 Q After we do the measure stage, "Come up</p> <p>3 here, do the tests again?"</p> <p>4 A Yes.</p> <p>5 Q Couple more questions. After the</p> <p>6 FiberWire runs through the coating, stretching</p> <p>7 process, is there a way to measure the amount of</p> <p>8 coating that is on the FiberWire?</p> <p>9 A No.</p> <p>10 Q Pearsalls typically doesn't do that.</p> <p>11 Okay. When the -- each FiberWire goes through two</p> <p>12 of the coating stretching processes?</p> <p>13 A That's correct.</p> <p>14 Q Is there a way to tell how much coating is</p> <p>15 applied in the second process versus the first</p> <p>16 process?</p> <p>17 A No.</p> <p>18 Q Is it less than the first process?</p> <p>19 Generally?</p> <p>20 A I don't think so.</p> <p>21 Q You don't think so? Well, I don't know.</p> <p>22 MR. TAMBURO: Objection, calls for</p> <p>23 speculation.</p> <p>24 MR. BONELLA: For the samples that are</p> <p>25 tested in the stretch and intermediate stage</p>	<p style="text-align: right;">121</p> <p>1 process?</p> <p>2 A They are looking for any defects within</p> <p>3 the braid, and they are giving it a measured length.</p> <p>4 Q A measured length on a spool?</p> <p>5 A Yes.</p> <p>6 Q What is the standard length?</p> <p>7 A It depends on the size. On US2 I believe</p> <p>8 it is 500 metres.</p> <p>9 Q And for US5?</p> <p>10 A It is 250.</p> <p>11 Q For the other sizes?</p> <p>12 A A thousand, 500, it depends on which size.</p> <p>13 Q For Size 0?</p> <p>14 A That is a thousand metres.</p> <p>15 Q 00 would probably be 2000. The 000 would</p> <p>16 be 3000. And 4000?</p> <p>17 A 10000.</p> <p>18 Q 0000 is 3000?</p> <p>19 A 3000.</p> <p>20 Q Okay, and after it undergoes this process</p> <p>21 then it goes back to the measuring in the QA in</p> <p>22 which measuring and testing is performed?</p> <p>23 A It is labeled as well here.</p> <p>24 Q It is labeled here? Okay. All right.</p> <p>25 Good. Thank you for your hospitality and showing us</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

227

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts
Corporation,
Plaintiff,
v.
ARTHREX, INC., a Delaware
Corporation,
Defendant.

Civil Action
No. 04-12457 PBS

HIGHLY
CONFIDENTIAL

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
12th January 2006

Condensed Copy

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p>244</p> <p>1 affect the testing results, the knot strength 2 testing results? 3 A Not generally it doesn't. 4 Q How about the testing? Can the testing 5 show variations in the testing results? 6 A Sometimes, yes. 7 Q But you don't know for sure why the 8 specifications changed? 9 MR. TAMBURIO: Objection. Asked and 10 answered. 11 A No. 12 MR. BONELLA: In Exhibit 316, do you see 13 the second column under number 5 FiberWire 14 lists a green product? 15 A Yes. 16 Q Similarly, Exhibit 317, the second column 17 lists a green number 5 FiberWire. Do you see that? 18 A Yes. 19 Q Has Pearsalls manufactured green number 5 20 FiberWire for commercial use? 21 A No. 22 Q The products shown on Exhibit 316, have 23 they all been manufactured for commercial use other 24 than the green FiberWire, number 5? 25 A Yes.</p>	<p>246</p> <p>1 Q Have all the products listed in Exhibit 2 318 been sold for commercial use? 3 A I don't know. 4 Q How was this chart prepared? 5 A It was prepared by myself and one of the 6 engineers at Arthrex. 7 Q Who? What Arthrex engineer? 8 A Tara Shanoville (Phonetic). 9 Q Why were -- how did you select certain 10 products for entry into this matrix? 11 A Most of them would have been what they had 12 been regarding. 13 Q What Arthrex had been ordering? 14 A Yes. 15 Q What about what Arthrex didn't order? 16 A Similarly they were listed. 17 Q Why were they listed? 18 A Because it may happen at some time or not. 19 Q Let's go through the chart, then. The 20 first product, PS 30, has that been manufactured for 21 commercial use? 22 A Yes. 23 Q How about the second product, PS C33? Has 24 that been manufactured for commercial use? 25 A Yes.</p>
<p>245</p> <p>1 Q How about Exhibit 317? Other than the 2 green number 5 FiberWire, have all those other 3 products been manufactured for commercial use? 4 A Whether they have been used for commercial 5 use, I don't really know, but these have been given 6 those references in case -- the product has been 7 made, and that is how they would order it. 8 Q They would order it -- Arthrex orders it 9 by the Pearsalls number? 10 A PS. 11 Q For example, Arthrex would order number 5 12 FiberWire but specifying DTSP 07? 13 A That's correct. 14 Q Next I will show you Exhibit 318. It is 15 a two-page document produced to us this morning 16 labeled, "Arthrex Products, Matrix of Label Product 17 and Development Codes". Do you recognize Exhibit 18 318? 19 (DePuy Mitek Exhibit 318 marked for identification) 20 A Yes. 21 Q What is Exhibit 318? 22 A What is it? 23 Q Yes. 24 A It is a matrix both for the development 25 and products for the use of FiberWire and TigerWire.</p>	<p>247</p> <p>1 Q How about PS 12/2? Has that been 2 manufactured for commercial use? 3 MR. TAMBURIO: Objection. Mike, is your 4 question, have they been sold commercially, 5 or -- because I think he testified that they 6 are prepared to be sold commercially, so when 7 you say, "Are they for commercial use", it is 8 a little confusing, because they are all really 9 for commercial use, but the question you may 10 want to ask is; have they been sold 11 commercially. I am not sure. 12 MR. BONELLA: What I am asking, 13 Mr. Hallett, is, typically Pearsalls sells 14 the -- the products just aren't samples, they 15 are providing to Arthrex. They sell the 16 product to -- they actually sell it to RK 17 Manufacturing or to Arthrex? 18 A They would have gone -- originally they go 19 to Arthrex. 20 Q They are sold to Arthrex? 21 A Yes. 22 Q Not RK? 23 A They go to RK, but if I made a developmen 24 they normally go to Arthrex first for verification. 25 Q Development, but when they are sold, the</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p>1 Q No you don't know?</p> <p>2 A I don't know.</p> <p>3 Q If you turn back to PR 8008, the 185/16</p> <p>4 product with the definition of braid that we have</p> <p>5 been talking about being a braid of two different</p> <p>6 materials braided together, with that definition,</p> <p>7 does the 185/16 have a braid of two different</p> <p>8 materials braided together?</p> <p>9 A No.</p> <p>10 Q 185/16 is two different materials because</p> <p>11 it has one material in the core and one material in</p> <p>12 the cover?</p> <p>13 A Yes.</p> <p>14 Q Mr. Hallett, I will show you DePuy Mitek</p> <p>15 Exhibit 323. It is PR 7507 through 7512. Do you</p> <p>16 see the Dyneema property sheet that is attached to</p> <p>17 the document?</p> <p>18 (DePuy Mitek Exhibit 323 marked for identification)</p> <p>19 A Yes.</p> <p>20 Q Have you ever seen that before? 7508</p> <p>21 through 7512?</p> <p>22 A Yes.</p> <p>23 Q Yes?</p> <p>24 A Yes.</p> <p>25 Q Is that the market literature from Dyneema</p>	<p>304</p> <p>1 samples 100% -- you see later down in the letter it</p> <p>2 says:</p> <p>3 "Can you build a 25% Dyneema/75%</p> <p>4 polyester blend in a size 2 that is very flexible</p> <p>5 (like the existing suture or the ethicon sample) and</p> <p>6 send it to me to test".</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q In the top paragraph does the sample of</p> <p>10 the Dyneema material, does that refer to a braid of</p> <p>11 100% Dyneema?</p> <p>12 A I can't remember.</p> <p>13 Q Do you recall ever making a construction</p> <p>14 that was 100% ultra high molecular weight</p> <p>15 polyethylene for Arthrex?</p> <p>16 A I can't remember.</p> <p>17 Q In November '98 is that when FiberWire was</p> <p>18 first being developed?</p> <p>19 A Yes.</p> <p>20 Q What did you understand Mr. Grafton to</p> <p>21 mean when he said:</p> <p>22 "Can you build a 25% Dyneema/75%</p> <p>23 polyester blend in Size 2 that is very flexible".</p> <p>24 What did you understand that to mean?</p> <p>25 A Yes, that he wanted a braid which was</p>
<p>305</p> <p>1 with respect -- I am sorry. Is 7508 through 7512</p> <p>2 marking literature from DSM on its Dyneema product?</p> <p>3 A That's correct.</p> <p>4 Q Does this describe the Dyneema that was</p> <p>5 used in FiberWire?</p> <p>6 A Yes.</p> <p>7 Q In the back it refers to the datasheet for</p> <p>8 SK65.</p> <p>9 A Hmm hmm.</p> <p>10 Q Was that SK65 ever used for FiberWire?</p> <p>11 A Yes.</p> <p>12 Q It was?</p> <p>13 A Sorry. I think it was SK64.</p> <p>14 Q That was used?</p> <p>15 A Yes, because the finer sizes, I don't</p> <p>16 think they did it in an SK65.</p> <p>17 Q Mr. Hallett, I am going to show you DePuy</p> <p>18 Mitek Exhibit 324. It is PR 6556. Is Exhibit 324</p> <p>19 a letter that you received from Mr. Grafton on about</p> <p>20 November 16th, 1998?</p> <p>21 (DePuy Mitek Exhibit 324 marked for identification)</p> <p>22 A Yes.</p> <p>23 Q It says in the letter to you that,</p> <p>24 "We...", referring to Arthrex, "... had tested the</p> <p>25 samples of the Dyneema material". Were those</p>	<p>307</p> <p>1 more -- not so stiff.</p> <p>2 Q As the 100% ultra high molecular weight</p> <p>3 polyethylene?</p> <p>4 A Yes.</p> <p>5 Q He wanted Pearsalls to try to put</p> <p>6 polyester with --</p> <p>7 A With the mixture.</p> <p>8 Q With a braid. He wanted -- let me finish</p> <p>9 the question before you answer.</p> <p>10 Mr. Grafton wanted Pearsalls to braid</p> <p>11 polyester with the ultra high molecular weight</p> <p>12 polyethylene so that the polyester could provide</p> <p>13 flexibility?</p> <p>14 A Yes.</p> <p>15 Q Next I will show you Exhibit 325. It is</p> <p>16 Bates number PR 6493. Do you recognize Exhibit 325</p> <p>17 as a letter from you to Mr. Grafton from November</p> <p>18 1998?</p> <p>19 (DePuy Mitek Exhibit 325 marked for identification)</p> <p>20 A Yes.</p> <p>21 Q And the letter said:</p> <p>22 "Please find enclosed a matrix of</p> <p>23 information of the samples that you took with you on</p> <p>24 your visit to Pearsalls, I will endeavour to proceed</p> <p>25 with the existing trial to match US2 Excel Braid</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p style="text-align: right;">308</p> <p>1 made by Ethicon, in Polyester construction. The next</p> <p>2 Poly/Dyneema samples should be with you by the end</p> <p>3 of the week".</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q Then you list four samples and the yarn</p> <p>7 type, and the first one is Dyneema and the next</p> <p>8 three are poly/Dyneema?</p> <p>9 A Yes.</p> <p>10 Q Was the first sample 100% Dyneema?</p> <p>11 A Yes.</p> <p>12 Q The second through fourth samples were</p> <p>13 a blend of, or a braid of polyester and Dyneema?</p> <p>14 A Correct.</p> <p>15 Q The 100% Dyneema had higher -- did they</p> <p>16 all have the same size? Do you know if these were</p> <p>17 all the same size, number 2, or --</p> <p>18 A I can't remember.</p> <p>19 Q When Pearsalls was developing the</p> <p>20 FiberWire, was it trying to -- was it comparing it</p> <p>21 against the Ethicon XL product?</p> <p>22 A I believe it was -- I don't know</p> <p>23 whether -- what it was comparing this to, but I was</p> <p>24 asked to make a braid compared with US5, a US5</p> <p>25 diameter.</p>	<p style="text-align: right;">310</p> <p>1 A Later part of last year. He still works</p> <p>2 at -- in Pearsalls.</p> <p>3 Q What do you mean by that?</p> <p>4 A He has been re-employed by a company</p> <p>5 called, "Novasive".</p> <p>6 Q Is that a company that is related to</p> <p>7 Pearsalls?</p> <p>8 A No.</p> <p>9 Q So, Mr. McLeod is not employed by</p> <p>10 Pearsalls?</p> <p>11 A No.</p> <p>12 Q No he's not employed?</p> <p>13 A He's not employed by Pearsalls.</p> <p>14 Q But he was?</p> <p>15 A He was.</p> <p>16 Q Do you see in his letter he says the first</p> <p>17 lot of PA 26 was produced as a development sample,</p> <p>18 DTPA 26?</p> <p>19 A Hmm hmm.</p> <p>20 Q Then he goes on to say, in the second</p> <p>21 paragraph, or the third paragraph, that:</p> <p>22 "Future orders will be supplied</p> <p>23 against the specification PA26B".</p> <p>24 Do you see what?</p> <p>25 A Yes.</p>
<p style="text-align: right;">309</p> <p>1 Q Yes, but do you see the reference to</p> <p>2 trying to match the US 2 XL braid made by Ethicon?</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q My question is; just generally in the</p> <p>6 development of FiberWire was Pearsalls comparing the</p> <p>7 products it was developing for FiberWire to</p> <p>8 Ethicon's XL products?</p> <p>9 A Yes.</p> <p>10 Q Was Pearsalls comparing the FiberWire</p> <p>11 products that it was developing to any other</p> <p>12 products during its development?</p> <p>13 A Not that I can remember.</p> <p>14 Q Next I will show you DePuy Mitek</p> <p>15 Exhibit 326. It is ARM2141 through 2147. First of</p> <p>16 all, I will see if you have any objections to the</p> <p>17 Arthrex Bates numbered document?</p> <p>18 (DePuy Mitek Exhibit 326 marked for identification)</p> <p>19 MR. TAMBURIO: No objection.</p> <p>20 MR. BONELLA: Mr. Hallett, is Mr. McLeod</p> <p>21 someone who works with you?</p> <p>22 A He did work for us.</p> <p>23 Q He has left Pearsalls?</p> <p>24 A Yes.</p> <p>25 Q When did he leave Pearsalls?</p>	<p style="text-align: right;">311</p> <p>1 Q In April 2001, is that when the -- it was</p> <p>2 decided to use the PA 6B code for number 2</p> <p>3 FiberWire?</p> <p>4 A It was decided, sorry?</p> <p>5 Q It was decided to use the PA 6B code for</p> <p>6 number 2 FiberWire?</p> <p>7 A Yes.</p> <p>8 Q If you turn to page ARM2146, do you have</p> <p>9 that page? ARM2146? Do you see it says:</p> <p>10 "The specification of the polyester</p> <p>11 is Type 712 and it is manufactured by KoSa GmbH &</p> <p>12 Company KG".</p> <p>13 A Yes.</p> <p>14 Q Is the polyester that Pearsalls has used</p> <p>15 for FiberWire always been manufactured by KoSa GmbH</p> <p>16 & Company KG?</p> <p>17 A Yes.</p> <p>18 Q Mr. Hallett, I will show you DePuy Mitek</p> <p>19 Exhibit 327, case number ARM2351, if you have no</p> <p>20 objections, Sal?</p> <p>21 (DePuy Mitek Exhibit 327 marked for identification)</p> <p>22 MR. TAMBURIO: No objections.</p> <p>23 MR. BONELLA: It says:</p> <p>24 "The first shipment of 61,000 metres of</p> <p>25 new Blue FiberWire 2 is leaving today to RK".</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p style="text-align: right;">340</p> <p>1 MR. TAMBURRO: Object to the form, and 2 seeking expert testimony. 3 A I don't know. 4 MR. BONELLA: You don't know? 5 A No. 6 Q What type of variation would you see to 7 make you think it was a big increase or a big 8 decrease between the dye stage and the measure 9 stage? 10 MR. TAMBURRO: Object to form. 11 A It could be up to about a kilo. 12 MR. BONELLA: How much? 13 A One kilo. 14 Q One kilo? 15 A Yes. 16 Q It could be more than that? 17 A Hmm hmm. 18 Q Could it be up to two to three kilos? 19 A I wouldn't think so, no. 20 Q You wouldn't think so. I will show you 21 Exhibit 339. It is Bates numbers PR 3730 through 22 3734 and it is entitled, "Pearsalls Sutures Results 23 for Batch 26866". Mr. Hallett, do you recognize 24 Exhibit 339 as a Pearsalls sutures Batch Record for 25 batch 26866?</p>	<p style="text-align: right;">342</p> <p>1 there between the dye stage and the intermediate 2 stage it went up by over 1 kilo? 3 A Yes. 4 Q And then at the measure stage it went down 5 over 1 kilo from the intermediate stage? 6 A Yes. 7 Q But the difference between the dye stage 8 and the measure stage was 0.11 kilos? 9 A Yes. 10 Q Do you know what might account for the 11 difference between the intermediate stage and the 12 measure stage? 13 MR. TAMBURRO: Object to the form. 14 A No. 15 MR. BONELLA: Do you know why the dye 16 stage and the measure stage were about the same 17 but the intermediate stage was about a kilo 18 greater, over a kilo greater? 19 MR. TAMBURRO: Object to form. 20 A No. 21 MR. BONELLA: Is that a concern, that 22 level of variation? 23 MR. TAMBURRO: Object to form. 24 A No. 25 MR. BONELLA: Why?</p>
<p style="text-align: right;">341</p> <p>1 (DePuy Mitek Exhibit 339 marked for identification) 2 A Yes. 3 MR. TAMBURRO: You don't have another copy 4 of that? 5 MR. BONELLA: No. I couldn't truck over 6 three copies of all of these. If you look at 7 the Pearsalls sutures Works Order for Exhibit 8 399 it refers to the product code of 37G500500. 9 A Yes. 10 Q That is the product code for number 2 blue 11 FiberWire? 12 A Yes. 13 Q Exhibit 339 is a record for batch 26866 14 for number 2 blue FiberWire? 15 A Yes. 16 Q If you look at the dye stage testing, the 17 average knot strength, knot pull was 15.64? 18 A Hmm hmm. 19 Q Then if you look at the intermediate stage 20 testing, it was 163990? 21 A Yes. 22 Q Then if you look at the measure stage 23 testing, it was 15.03? 24 A Yes. 25 Q Do you know what account -- do you see</p>	<p style="text-align: right;">343</p> <p>1 A Because I think you will see it reaches 2 the requirements of that specific size. 3 Q You don't know what would cause it to go 4 down between the intermediate stage testing and the 5 measure stage testing? 6 MR. TAMBURRO: Objection. Asked and 7 answered. 8 A It could be the operator. 9 MR. BONELLA: Just the operator? 10 A Yes. 11 Q It could be how they tie the knot? 12 A Yes. 13 Q I will show you Exhibit 340. It is PR 14 4308 through PR 4321. It is Pearsalls sutures 15 results for batch 25330. Do you recognize Exhibit 16 340 as the Batch Record for batch 5330? 17 (DePuy Mitek Exhibit 340 marked for identification) 18 A Yes. 19 MR. TAMBURRO: Have you got another copy of 20 that? 21 MR. BONELLA: No. If you go to the back 22 you will see the product code is 25330? 23 A Correct. 24 Q Exhibit 340 is the batch record for number 25 2 FiberWire blue, batch 25330?</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p style="text-align: right;">344</p> <p>1 A Yes.</p> <p>2 Q If you look at this document you will see</p> <p>3 that the dye average -- the average knot strength at</p> <p>4 the dye stage was 16.26; right?</p> <p>5 A That's correct.</p> <p>6 Q And then at the intermediate stage, the</p> <p>7 average knot pull strength was 16.53, right?</p> <p>8 A Correct.</p> <p>9 Q And then at the measure stage, the average</p> <p>10 knot strength was 16.75?</p> <p>11 A That's correct.</p> <p>12 Q So, between the dye stage and the</p> <p>13 intermediate stage, the difference in the knot pull,</p> <p>14 average knot pull was less than 0.3 kilos?</p> <p>15 MR. TAMBURIO: Object to form.</p> <p>16 A Correct.</p> <p>17 MR. BONELLA: And the difference between</p> <p>18 the average knot strength between the</p> <p>19 intermediate stage and the measure stage was</p> <p>20 less than 0.3 kilos as well; right?</p> <p>21 A That's correct.</p> <p>22 Q Are these numbers, this 16.26, 16.53,</p> <p>23 16.75, are they considered to be all about the same,</p> <p>24 based on the tolerances?</p> <p>25 A That's right.</p>	<p style="text-align: right;">346</p> <p>1 MR. TAMBURIO: Object to form and seeking</p> <p>2 expert testimony. Do you have a copy for</p> <p>3 counsel, Mr. Bonella?</p> <p>4 MR. BONELLA: I have one copy of the Batch</p> <p>5 Records. I didn't even bring one for me.</p> <p>6 A That is the operator testing.</p> <p>7 Q Operator testing?</p> <p>8 A Hmm hmm.</p> <p>9 Q Do you know what would account for the</p> <p>10 increase in average knot pull strength between the</p> <p>11 intermediate stage and the measure stage?</p> <p>12 MR. TAMBURIO: Same objection.</p> <p>13 A Yes.</p> <p>14 Q What is that?</p> <p>15 A Because it has been coated.</p> <p>16 Q Coated?</p> <p>17 A Hmm hmm.</p> <p>18 Q If it increases when it is coated, we saw</p> <p>19 other ones where it decreased when it was coated?</p> <p>20 A Very slightly.</p> <p>21 Q In Exhibit 339, the average knot pull</p> <p>22 decreased between intermediate and measure from 16.9</p> <p>23 to 15.53, right? That was a decrease of 1.4, right?</p> <p>24 A Yes.</p> <p>25 Q Do you know why that would be?</p>
<p style="text-align: right;">345</p> <p>1 Q Next I will show you Exhibit 341. It is</p> <p>2 PR 3778 through 3791 entitled, "Pearsalls Sutures</p> <p>3 Results for Batch 5899", do you recognize Exhibit</p> <p>4 341 as the Batch Record results for batch 5899?</p> <p>5 (DePuy Mitek Exhibit 341 marked for identification).</p> <p>6 A Yes.</p> <p>7 Q Would you turn to the Work Order on PR</p> <p>8 3791? Do you see the product code is 35G500?</p> <p>9 A Correct.</p> <p>10 Q Batch 25891 is for number 2 blue</p> <p>11 FiberWire?</p> <p>12 A Yes.</p> <p>13 Q If you look at the testing you will see</p> <p>14 that the average knot pull strength at the dye stage</p> <p>15 was 15.61, correct?</p> <p>16 A That's correct.</p> <p>17 Q The average knot pull strength at</p> <p>18 intermediate testing was 14.83?</p> <p>19 A That's correct.</p> <p>20 Q The average knot strength at the measure</p> <p>21 stage was 16.87?</p> <p>22 A That's correct.</p> <p>23 Q Do you know what would account for the</p> <p>24 decrease in average knot pull strength between the</p> <p>25 dye stage and the intermediate stage?</p>	<p style="text-align: right;">347</p> <p>1 A No. Operator.</p> <p>2 Q What accounts for the -- so, with Exhibit</p> <p>3 341 you are saying the decrease between the dye and</p> <p>4 the intermediate stage was due to coating?</p> <p>5 MR. TAMBURIO: Objection. Asked and</p> <p>6 answered.</p> <p>7 A The increase.</p> <p>8 MR. BONELLA: I am sorry, the increase,</p> <p>9 but didn't it go from -- it was 15 -- in</p> <p>10 Exhibit 341, the average knot pull in dye was</p> <p>11 15.361, right?</p> <p>12 A Yes.</p> <p>13 Q That is before coating?</p> <p>14 A Hmm hmm.</p> <p>15 Q And the average knot pull at the</p> <p>16 intermediate stage was 14.483, right, and that is</p> <p>17 after coating?</p> <p>18 A Hmm hmm.</p> <p>19 Q What caused the knot pull to go down from</p> <p>20 the dye stage to the intermediate stage?</p> <p>21 MR. TAMBURIO: Objection, calls for expert</p> <p>22 testimony, asked and answered. Calls for</p> <p>23 speculation.</p> <p>24 A I don't know.</p> <p>25 MR. BONELLA: You don't know?</p>

CONFIDENTIAL- NON-PATENT ATTORNEYS EYES ONLY

<p>348</p> <p>1 A No.</p> <p>2 Q How do you know at the measure stage it</p> <p>3 was -- in Exhibit 341 it was 16.482; right?</p> <p>4 A So it is increased.</p> <p>5 Q Check numbers. But how do you know -- it</p> <p>6 is increased. There is nothing done with the suture</p> <p>7 between the intermediate stage and the measure stage</p> <p>8 that would change the property of the suture; right?</p> <p>9 A Hmm hmm.</p> <p>10 Q Right?</p> <p>11 A Yes.</p> <p>12 Q Yes, I am correct?</p> <p>13 A Yes, you are correct.</p> <p>14 Q How do you know which one's right, the</p> <p>15 decreased one at the intermediate stage or the</p> <p>16 increased one at the end stage?</p> <p>17 MR. TAMBURRO: Calls for expert testimony</p> <p>18 and object to the form.</p> <p>19 MR. BONELLA: Or were they all about the</p> <p>20 same?</p> <p>21 A They all vary.</p> <p>22 Q Well, if you look at the testing you</p> <p>23 cannot really say -- are they all within the</p> <p>24 tolerance of the testing so that you cannot really</p> <p>25 say that one of these values is greater than the</p>	<p>350</p> <p>1 MR. TAMBURRO: I think he knows only what</p> <p>2 I know. He wasn't there watching it when it</p> <p>3 was done.</p> <p>4 MR. BONELLA: All right. I will take your</p> <p>5 representation that it is what it is.</p> <p>6 I will show you DePuy Mitek Exhibit 343.</p> <p>7 It is a three-page document test recorded</p> <p>8 summary and sign-off sheet from Arthrex. Sal,</p> <p>9 do you have any problems in me showing him</p> <p>10 Exhibit 343? It was disclosed to J&J as</p> <p>11 non-contentious.</p> <p>12 MR. TAMBURRO: No objection.</p> <p>13 MR. BONELLA: Mr. Hallett, I am showing</p> <p>14 you Exhibit 343. I believe it has Brian</p> <p>15 Hallett's writing on the first page, I believe</p> <p>16 it is a document from Arthrex. Have you ever</p> <p>17 seen this document before?</p> <p>18 (DePuy Mitek Exhibit 343 marked for identification)</p> <p>19 A Yes.</p> <p>20 Q You have?</p> <p>21 A Hmm hmm.</p> <p>22 Q When did you see it?</p> <p>23 A Sometime last year.</p> <p>24 Q And why did you see it?</p> <p>25 A I think it was describing or showing the</p>
<p>349</p> <p>1 other?</p> <p>2 MR. TAMBURRO: Objection, calls for expert</p> <p>3 testimony and speculation.</p> <p>4 A Yes.</p> <p>5 MR. BONELLA: That's correct?</p> <p>6 A Yes.</p> <p>7 MR. TAMBURRO: Mike, this is the</p> <p>8 once-passed coating sample of US2 FiberWire.</p> <p>9 We don't have a Bates number but I will send</p> <p>10 you a Bates number by e-mail. It is a little</p> <p>11 capsule labeled, "Sample Pearsalls Limited blue</p> <p>12 FiberWire single coating 15 metres US2 batch</p> <p>13 number 28790".</p> <p>14 MR. BONELLA: Okay. We will mark it as</p> <p>15 DP342 and ask Mr. Hallett if you can identify</p> <p>16 DePuy Mitek Exhibit 342, or take counsel's</p> <p>17 representation that it is number 2 blue</p> <p>18 FiberWire that has been run through the</p> <p>19 coating, stretching and drying process only one</p> <p>20 time. Is that correct?</p> <p>21 (DePuy Mitek Exhibit 342 marked for identification)</p> <p>22 MR. TAMBURRO: That is my understanding</p> <p>23 yes.</p> <p>24 MR. BONELLA: Can he testify to that?</p> <p>25 Does he know?</p>	<p>351</p> <p>1 test procedure for doing a braid load on the loops.</p> <p>2 Q On what?</p> <p>3 A On the loop.</p> <p>4 Q If you look at the top it says the</p> <p>5 description of the procedure on the first page is</p> <p>6 number 2 FiberWire 2174 coated and uncoated USIPG</p> <p>7 dyed, and the date is February 16, '04, and the type</p> <p>8 of test it says, knot tiedown, and it says:</p> <p>9 "The test objective: To determine</p> <p>10 the peak force required to advance a single half</p> <p>11 hitch using coated and uncoated Fiberwire suture".</p> <p>12 Do you see that?</p> <p>13 A Hmm hmm.</p> <p>14 Q The test method is described as:</p> <p>15 "The 50lb load cell was attached to</p> <p>16 the MTS Sintech 1/S and calibrated. A custom</p> <p>17 fixture as shown was used to simulate knot tying</p> <p>18 that would occur clinically. The top end of the</p> <p>19 suture was clamped in a custom fixture that was</p> <p>20 attached to the load cell, and then a single half</p> <p>21 hitch was tied around a guide block such that the</p> <p>22 loop length was consistent between samples.</p> <p>23 A weight of .375 kg was then attached to the free</p> <p>24 end of the suture in order to tension the loop.</p> <p>25 Care was taken to tension the legs of the suture</p>

BROOKSTEIN DECLARATION EXHIBIT 6

11/16/1998 18:24 941-643-6218

ARTHREX SCHMIEDING

PAGE 61

Arthrex. 

November 16, 1998

Brian Hallert
Pearsalls Sutures
Tanager Street, Taunton
Somerset TA1 1RY, England

FAX 011441823336824

Dear Brian:

We have tested the samples of the Dyneema material I got from you when I was at Pearsalls. They have very good tensile strength but as you mentioned they are larger in diameter than the size 2 suture we presently use. We do need for our test record more info on the 4 samples. If you could give me some basic specifications for our records I would appreciate it.

Can you build a 25% Dyneema / 75% polyester blend in a size 2 that is very flexible (like the existing suture or the ethicon sample) and send it to me to test? If we can get this blend correct, we will have a terrific advancement in suture for our soft tissue anchors.

Thank you

Don Grafton
V. P. Engineering
Arthrex Inc.

DEPUY MITEK
EXHIBIT 324
04cv12457

Arthrex, Inc. • 1300 South 17th Avenue, Suite 100 • Fort Lauderdale, FL 33316 • Tel: (954) 644-9559 • Fax: (954) 644-6218 • Website: www.arthrex.com

PR 06556
Confidential - Outside Attorneys' Eyes Only

BROOKSTEIN DECLARATION EXHIBIT 7

TO :Arthrex

ATTN: Don Grafton

FROM : Brian Hallett

DATE : 16/11/98

SUBJECT : POLYESTER - DYNEEMA -(Braids)

Dear Don,

Please find enclosed a matrix of information of the samples that you took with you on your visit to Pearsalls , I will endeavour to proceed with the existing trial to match the US2 Excel Braid made by Ethicon, in Polyester construction.
The next Poly/Dyneema sample should be with you by the end of the week

Yarn	Dt-no	Runnage Mt/ Kg	St/pull KG	Diameter MM	Extention %	PPI
Dyneema	DAOI	3034	23.12	0.714	24.39	46
Poly/Dyneema	PA13	2984	36.27	0.702	18.33	48
Poly/Dyneema	PA14	3331	34.95	0.639	18.83	48
Poly/Dyneema	PA14 Stretch	3469	36.41	0.628	14.32	48

Kind regards

Brian Hallett
Product Development Manager



PR 06493
Confidential - Outside Attorneys' Eyes Only

BROOKSTEIN DECLARATION EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

DEPOSITION OF:

PETER DREYFUSS

DATE:

September 16, 2005

TIME:

8:59 a.m. to 1:54 p.m.

LOCATION:

The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY:

Plaintiff

REPORTER:

Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER:

Les Smoak, CLVS

<p>1 I do on sutures.</p> <p>2 Q. But Arthrex doesn't specifically test for how</p> <p>3 much coating has been applied on FiberWire sutures from</p> <p>4 Pearsalls?</p> <p>5 A. No, not that I'm aware of.</p> <p>6 Q. Has Arthrex ever rejected a batch of bulk sutures</p> <p>7 based on the amount of coating that's been applied to any</p> <p>8 FiberWire sutures?</p> <p>9 A. Not that I know of.</p> <p>10 Q. Okay. And then -- Okay. Now back to ARM 8784 in</p> <p>11 Exhibit 102, we've stretched and coated the suture or the</p> <p>12 braid, and what's the next step?</p> <p>13 A. It looks -- final inspection and measuring, which</p> <p>14 would be QC.</p> <p>15 Q. And how is that final inspection QC performed?</p> <p>16 A. There's, as I understand, there's various steps.</p> <p>17 Mechanical measuring, and there's a -- whatever -- by</p> <p>18 feel, measuring for any imperfections.</p> <p>19 Q. Popping maybe? Are you familiar with that term?</p> <p>20 A. Not exactly.</p> <p>21 Q. Okay.</p> <p>22 A. Just making sure the suture is homogenous,</p> <p>23 consistent, and strong.</p> <p>24 Q. Now you said mechanical measuring. What kind of</p> <p>25 mechanical measuring is used in the inspection process for</p>	<p>94</p> <p>1 it related to the 16-carrier bobbin applies to Arthrex's</p> <p>2 FiberWire No. 2 as sold in AR-7201; right?</p> <p>3 A. Correct.</p> <p>4 MR. FALKE: Why don't we break for lunch.</p> <p>5 MR. TAMBURRO: Sounds good.</p> <p>6 VIDEOGRAPHER: Going off the record. We're off</p> <p>7 (A lunch break was held from 11:47 a.m. to 12:47</p> <p>8 p.m.)</p> <p>9 VIDEOGRAPHER: Back on the record.</p> <p>10 BY MR. FALKE:</p> <p>11 Q. Okay, Mr. Dreyfuss, do you want to look at</p> <p>12 Exhibit 120 for a minute. The coating that's shown in</p> <p>13 Exhibit 120 and the bath of the coating, is that bath</p> <p>14 comprised of 100 percent MED-2174?</p> <p>15 MR. TAMBURRO: Object to the form.</p> <p>16 A. I believe it is, yes.</p> <p>17 Q. Okay. So there's no solvent or any other</p> <p>18 material used possibly to dissolve the coating?</p> <p>19 A. I'm not aware of it, no.</p> <p>20 Q. Okay. But you understand the coating -- the bath</p> <p>21 of MED-2174 as used in the coating process for Arthrex's</p> <p>22 FiberWire sutures to be 100 percent MED-2174?</p> <p>23 A. I believe so.</p> <p>24 Q. Also, if we could go back -- That's okay. I'd</p> <p>25 like you to take that sheet of paper there in front of</p>
<p>95</p> <p>1 Arthrex's FiberWire sutures?</p> <p>2 A. There's a -- they actually measure the diameter</p> <p>3 per a certain procedure or a certain approved protocol</p> <p>4 that you measure the diameter at several places, several</p> <p>5 locations along a certain piece of suture to get an</p> <p>6 average diameter.</p> <p>7 Q. Does Arthrex provide specifications to Pearsalls</p> <p>8 for the inspection process of its FiberWire sutures?</p> <p>9 A. Yes.</p> <p>10 Q. And what specifications are those?</p> <p>11 A. Drawing -- on the drawing specifications, I would</p> <p>12 assume.</p> <p>13 Q. Okay.</p> <p>14 A. And possibly in an inspection procedure that we</p> <p>15 have written up in a document form.</p> <p>16 Q. Okay. And once the braid or the bulk suture has</p> <p>17 been inspected and measured, what happens next?</p> <p>18 A. If approved, I would assume it would be either --</p> <p>19 well, if it's part of an order, I would assume it's then</p> <p>20 be shipped to the customer, which would be ...</p> <p>21 Q. And then that customer -- Strike that.</p> <p>22 The braiding process that we've talked about with</p> <p>23 respect -- Strike that.</p> <p>24 The manufacturing process that we've talked about</p> <p>25 with respect to ARM 8784 in Exhibit 102, that testimony as</p>	<p>97</p> <p>1 you, and if you could, could you draw a cross-section of</p> <p>2 Arthrex's No. 2 FiberWire?</p> <p>3 A. I can -- I can try, yes.</p> <p>4 Q. And list, please -- you know -- the various</p> <p>5 materials and what not. And I'm going to mark your</p> <p>6 drawing of a cross-section of Arthrex's No. 2 FiberWire</p> <p>7 with Exhibit No. 121.</p> <p>8 (DePuy Mitek Exhibit No. 121, drawing of Peter</p> <p>9 Dreyfuss of the Approximate Cross-Section of Arthrex</p> <p>10 2-0 FiberWire, was marked for identification.)</p> <p>11 A. I luckily got eight. Oh. I approximated the</p> <p>12 numbers.</p> <p>13 Q. Okay. Did you say you drew eight?</p> <p>14 A. I drew an eight -- a version of an eight-carrier</p> <p>15 braid.</p> <p>16 Q. Okay. And that would be a cross-section then of</p> <p>17 Arthrex's 2-0 FiberWire suture?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. So we're going to remark Exhibit 121 as a</p> <p>20 drawing of Arthrex's 2-0 FiberWire suture; is that</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And if you could just label that and</p> <p>24 initial and date it, please.</p> <p>25 A. (Witness complying).</p>

<p>98</p> <p>1 Q. And I don't know if you did, but could you please 2 label the core and the cover?</p> <p>3 A. Yes, I did.</p> <p>4 Q. Okay.</p> <p>5 A. I was doing a core with three parts to represent 6 the No. 2 suture. But since it's an 0, I'm not exactly 7 sure how many yarns are made up of the core, but they're 8 all UHMWP --</p> <p>9 Q. Okay.</p> <p>10 A. -- if that's acceptable.</p> <p>11 Q. Okay. Yeah. Let me just take a look at it, 12 please.</p> <p>13 Okay. So but other than the core, which you're 14 not quite sure of how many yarns make up the core on the 15 2-0, this outside accurately represents the cover or the 16 sheath of the Arthrex 2-0 FiberWire?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And as you have shown, going around the 19 cover or the sheath, the materials alternate PET, ultra 20 high molecular weight polyethylene, PET, ultra high 21 molecular weight polyethylene, et cetera?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Now within the sheath or the cover -- 24 Well, first could you just label the sheath and the cover 25 for me?</p>	<p>100</p> <p>1 time? Ever since Arthrex is manufacturing a 2-0 2 FiberWire, it's been using this configuration as shown in 3 121?</p> <p>4 A. Yes.</p> <p>5 Q. Okay.</p> <p>6 A. (Witness complying).</p> <p>7 Q. And I'm going to mark your drawing of Arthrex's 8 No. 2 FiberWire suture as DePuy Mitek Exhibit 122. 9 (DePuy Mitek Exhibit No. 122, drawing of Peter 10 Dreyfuss of the Approximate Cross-Section of No. 2 11 FiberWire, was marked for identification.)</p> <p>12 Q. Can I take a look at it, please?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And so this shows a core made up of three 15 ultra high molecular weight polyethylene yarns twisted 16 together and then a cover or sheath composed of 17 alternating yarns of ultra high molecular weight 18 polyethylene and PET; is that right?</p> <p>19 A. Correct.</p> <p>20 Q. And the PET and ultra high molecular weight 21 polyethylene that make up the sheath or cover of Arthrex's 22 FiberWire No. 2 are in direct contact with each other; is 23 that right?</p> <p>24 A. Yes.</p> <p>25 Q. Okay. And they're intertwined around each other;</p>
<p>99</p> <p>1 A. (Witness complying).</p> <p>2 Q. Are the individual yarns in the cover or sheath 3 of the Arthrex 2-0 FiberWire as shown in 121 in contact 4 with each other, meaning is the ultra high molecular 5 weight polyethylene yarn connected to the neighboring PET 6 yarn?</p> <p>7 MR. TAMBURIO: Object to the form.</p> <p>8 A. They're all interdigitated. I'm sure there's 9 contact between them.</p> <p>10 Q. Intertwined?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. So there is contact then between the 13 neighboring or adjacent PET and ultra high molecular 14 weight --</p> <p>15 A. Yes.</p> <p>16 Q. -- polyethylene yarns and the sheath or cover?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Next, if you could, could you please draw 19 a cross-section of Arthrex's No. 2 FiberWire?</p> <p>20 And -- I'm sorry. But before we go on, does 21 Exhibit 121 reflect the construction or the structure of 22 the 2-0 FiberWire as it's always been?</p> <p>23 A. To the best of my knowledge, yes.</p> <p>24 Q. Okay. So the construction with the structure as 25 shown in 121 of a 2-0 FiberWire suture hasn't changed over</p>	<p>101</p> <p>1 right?</p> <p>2 A. They're braided.</p> <p>3 Q. Okay. Is that intertwining or --</p> <p>4 A. Yes, they're ...</p> <p>5 Q. Okay. And does Exhibit 122 accurately reflect 6 the construction of Arthrex's FiberWire No. 2 currently 7 and since its release or since it was first sold by 8 Arthrex?</p> <p>9 MR. TAMBURIO: Object to the form.</p> <p>10 A. I believe so.</p> <p>11 Q. Okay. Could you mark or title Exhibit 122?</p> <p>12 A. (Witness complying).</p> <p>13 Q. And next I was going to ask you to draw a 14 cross-section of the No. 5 Arthrex FiberWire suture, which 15 I believe is the same as Exhibit 122 that you have just 16 drawn with the exception of possibly the number of yarns 17 that comprise the core; is that right?</p> <p>18 A. I believe that would be correct.</p> <p>19 Q. Okay. And -- but the outside of the cover or 20 sheath of the Arthrex FiberWire No. 2 is the same as the 21 cover or sheath of the Arthrex FiberWire No. 2; right?</p> <p>22 A. In the manner of braiding, yes.</p> <p>23 Q. Right.</p> <p>24 MR. TAMBURIO: Object to the form.</p> <p>25 Q. In the manner as you have shown in Exhibit</p>

<p>102</p> <p>1 No. 122?</p> <p>2 A. Yes.</p> <p>3 Q. I misspoke there, but the outside or the cover of</p> <p>4 the Arthrex FiberWire No. 5 is the same as the cover or</p> <p>5 sheath of the Arthrex FiberWire No. 2; is that correct?</p> <p>6 A. That's correct.</p> <p>7 Q. Okay. The same in terms of configuration and</p> <p>8 contact and intertwining; right?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Next, if I can ask you to draw the</p> <p>11 cross-section of Arthrex's No. 0 FiberWire.</p> <p>12 A. Let's see.</p> <p>13 Q. And I believe you testified earlier, and correct</p> <p>14 me if I'm wrong --</p> <p>15 A. Twelve.</p> <p>16 Q. -- that there's twelve carriers?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. And I also believe you testified earlier</p> <p>19 that you weren't sure about how many yarns make up the</p> <p>20 core in Arthrex's Size 0 FiberWire; is that right?</p> <p>21 A. That's correct.</p> <p>22 Q. Okay.</p> <p>23 A. I'm sorry; would you give me the number again?</p> <p>24 MR. TAMBURO: Here.</p> <p>25 A. All right.</p>	<p>104</p> <p>1 Dreyfuss of the Approximate Cross-Section of Size 3-0</p> <p>2 FiberWire, was marked for identification.)</p> <p>3 Q. And just so the record's clear, all these hand</p> <p>4 drawings that you have done so far, when it says UHMW,</p> <p>5 that means ultra high molecular weight polyethylene?</p> <p>6 A. Correct.</p> <p>7 Q. Okay. And what you've shown is that Arthrex's</p> <p>8 No. 3-0 FiberWire has alternating yarns of PET and ultra</p> <p>9 high molecular weight polyethylene?</p> <p>10 A. Correct.</p> <p>11 Q. And that those neighboring yarns and the sheath</p> <p>12 or cover contact each other?</p> <p>13 A. Correct.</p> <p>14 Q. And they're in the same -- you know --</p> <p>15 intertwining manner as Exhibits 123, 122, and 121?</p> <p>16 A. Correct.</p> <p>17 Q. And now if you could just draw for me a</p> <p>18 cross-sectional drawing of Arthrex's 4-0 FiberWire suture,</p> <p>19 please. And I'm going to mark your drawing of Arthrex's</p> <p>20 4-0 FiberWire suture with DePuy Mitek Exhibit 125.</p> <p>21 A. (Witness complying).</p> <p>22 (DePuy Mitek Exhibit No. 125, drawing of Peter</p> <p>23 Dreyfuss of the Approximate Cross-Section of Size 4-0</p> <p>24 FiberWire, was marked for identification.)</p> <p>25 Q. And I believe what you've shown in Exhibit 125 is</p>
<p>103</p> <p>1 Q. Now I'm going to mark your drawing of a</p> <p>2 cross-section of Arthrex's No. 0 FiberWire with DePuy</p> <p>3 Mitek Exhibit 123.</p> <p>4 (DePuy Mitek Exhibit No. 123, drawing of Peter</p> <p>5 Dreyfuss of the Approximate Cross-Section of Size 0</p> <p>6 FiberWire, was marked for identification.)</p> <p>7 Q. And I believe what you've drawn in Exhibit 123 is</p> <p>8 that the cover or sheath of the Arthrex No. 0 FiberWire</p> <p>9 has alternating yarns of PET and ultra high molecular</p> <p>10 weight polyethylene; is that right?</p> <p>11 A. Correct.</p> <p>12 Q. And that -- and that those neighboring yarns in</p> <p>13 the sheath or cover are in contact with each other?</p> <p>14 A. Correct.</p> <p>15 Q. And in the same configuration and intertwining</p> <p>16 manner as Exhibits 122 and 121?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. Could you draw for me a cross-section of</p> <p>19 Arthrex's FiberWire 3-0 suture? I believe you testified</p> <p>20 earlier that it's eight carriers.</p> <p>21 A. Thank you.</p> <p>22 Q. And I'm going to label your cross-section drawing</p> <p>23 of Arthrex's FiberWire No. 3 suture with DePuy Mitek</p> <p>24 Exhibit 124.</p> <p>25 (DePuy Mitek Exhibit No. 124, drawing of Peter</p>	<p>105</p> <p>1 that, one, there's no core in the 4-0 FiberWire; right?</p> <p>2 A. Correct.</p> <p>3 Q. And that the sheath or cover is made up of</p> <p>4 intertwining yarns of ultra high molecular weight</p> <p>5 polyethylene and PET?</p> <p>6 A. Correct.</p> <p>7 Q. And that the neighboring yarns within the cover</p> <p>8 or sheath are in contact with each other?</p> <p>9 A. Correct.</p> <p>10 Q. Okay. Do Exhibits 123, 124, and 125 show not</p> <p>11 only the present-day but the configuration of the</p> <p>12 FiberWire sutures as sold in the past?</p> <p>13 A. Yes, to the best of my knowledge and --</p> <p>14 Q. In other words, there hasn't been any different</p> <p>15 configurations of Arthrex's 0, 3-0, and 4-0 FiberWire</p> <p>16 sutures?</p> <p>17 A. I'm not for certain on the 4-0.</p> <p>18 Q. Okay. But for the 2-0 and the -- or for the 0</p> <p>19 and the 3-0 you are?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And I don't think I asked you this, but in</p> <p>22 Exhibit 125, the alternating sheaths -- alternating yarns</p> <p>23 and the sheath or cover are in intertwining contact like</p> <p>24 Exhibits 124, 123, 122, and 121?</p> <p>25 A. Yes.</p>

106

1 Q. Okay. Now what I'd like you to draw is a
2 cross-section of Arthrex's TigerWire suture.
3 A. Okay. Which size? Actually, there's --
4 Q. That's a good question. How many sizes of
5 TigerWire are there?
6 A. No, technically, there's only one.
7 Q. Okay. Is that a No. 2 size?
8 A. Correct.
9 Q. Okay. So just to rephrase, can you please draw a
10 No. 2 TigerWire as sold by Arthrex?
11 A. (Witness complying).
12 Q. And I'm going to mark your drawing of No. 2
13 TigerWire as sold by Arthrex with DePuy Mitek Exhibit 126.
14 (DePuy Mitek Exhibit No. 126, drawing of Peter
15 Dreyfuss of the Approximate Cross-Section of Size 2
16 TigerWire, was marked for identification.)
17 Q. Do you know how many carriers are in the Arthrex
18 No. 2 TigerWire?
19 A. Sixteen.
20 Q. Sixteen. So the configuration of the sheath or
21 cover in Arthrex's No. 2 TigerWire is exactly the same as
22 the sheath or cover as Arthrex's No. 2 FiberWire with the
23 exception that one of the PET carriers has been replaced
24 with a black nylon carrier?
25 A. Correct.

107

1 Q. Okay. So the sheath has alternating yarns made
2 up of ultra high molecular weight and polyester or PET
3 with the exception of one carrier that is black nylon?
4 A. Correct.
5 Q. Okay. And the adjacent yarns in the sheath are
6 in contact with each other in the same intertwining manner
7 as Exhibits 125, 124, 123, 122, and 121?
8 A. Correct.
9 Q. Okay. All right. Thank you.
10 Okay. Now I'd like to talk about FiberTape.
11 Could you explain to me the process that Pearsalls goes
12 through to manufacture FiberTape from the stage of
13 individual yarns?
14 Actually -- Do you know what? I might have a
15 document here that would help you out.
16 I'm going to show you what's being marked as
17 DePuy Mitek Exhibit 127. It's a document with Bates
18 numbers ARM 8847 through 9091.
19 One is double-sided; one isn't. That one goes to
20 Sal. No. I'm sorry. That one goes to Sal.
21 Okay. We're talking about Exhibit No. 127.
22 (DePuy Mitek Exhibit No. 127, Technical File
23 Arthrex FiberWire Volume 2, was marked for
24 identification.)
25 Q. Have you seen Exhibit 127 before?

108

1 A. Not to my knowledge, no. Not ...
2 Q. If you could turn to Page ARM 9003. Now you can
3 -- I'm sorry; it's the page before also, ARM 9002.
4 I'm going to ask the question again. If you need
5 to reference this page, go right ahead. Can you explain
6 to me the process that Pearsalls goes through to
7 manufacture Arthrex's FiberTape?
8 A. In short, a tape component is -- They use the --
9 a braiding machine? But the carriers are configured in
10 such a way that the braids don't -- the ends of the
11 carriers don't actually cross, and, therefore, it's an
12 open braid which, when it's taken up on the takeup spool
13 it flattens out, makes a tape. That tape is then
14 incorporated -- stitched into a piece of FiberWire suture
15 along its length with a length of -- the length of
16 FiberWires on the ends which have no tape. The middle
17 portion of the construct is FiberWire and FiberTape
18 interstitched, and the ends and the FiberTape ends within
19 the FiberWire, and then there's ends of FiberWire outside
20 of that.
21 Q. Okay. So does Arthrex's FiberTape include an
22 Arthrex No. 2 FiberWire suture?
23 A. Yes.
24 Q. And does it include the Arthrex FiberWire No. 2
25 suture as depicted in Exhibit 122?

109

1 A. Yes.
2 Q. Can you just draw for me, please, the
3 cross-section of an Arthrex FiberWire Tape as --
4 A. Can I -- May I simplify it? Representative of
5 FiberWire and tape without all ...
6 Q. Sure. You can start about that, and if I'm
7 confused or need more, then I'll let you know. But you
8 can start with that.
9 MR. TAMBURIO: I'm going to object to this line of
10 questioning regarding FiberTape as outside the scope
11 of the notice, which seems to be limited to FiberWire
12 sutures.
13 MR. FALKE: Well ... I think we defined in our
14 first set of either documentary requests or
15 Interrogatories as FiberWire including FiberWire or
16 any product that includes FiberWire, but your
17 objection is -- you know -- it's your objection.
18 MR. TAMBURIO: I thought I heard a different
19 definition today of FiberWire suture that would not
20 include FiberWire Tape.
21 MR. FALKE: Right. But I think the notice was
22 probably using the definitions of the other discovery,
23 not necessarily definitions of mine, but --
24 MR. TAMBURIO: Fine. I just wanted to note my
25 objection.

<p>122</p> <p>1 Q. What is FiberStick, sold under AR-7209?</p> <p>2 A. FiberStick is a length of FiberWire that has a --</p> <p>3 a long length of it that is tipped or stiffened with the</p> <p>4 Loc-Tite, and it makes it easier to perform certain</p> <p>5 actions with.</p> <p>6 Q. Other than the difference in the length of</p> <p>7 stiffening on the end of FiberStick, is there any other</p> <p>8 difference in any way between FiberStick AR-7209 and the</p> <p>9 blue FiberWire in AR-7201?</p> <p>10 A. Just the overall length is longer.</p> <p>11 Q. Okay. So is the structure and configuration in</p> <p>12 FiberStick AR-7209 the same as the No. 2 FiberWire in</p> <p>13 Exhibit 122?</p> <p>14 MR. TAMBURIO: Object to form.</p> <p>15 A. Yes.</p> <p>16 Q. Does the No. 2 FiberSnare in AR-7209SN have the</p> <p>17 same structure and configuration as the No. 2 FiberWire in</p> <p>18 Exhibit 122?</p> <p>19 MR. TAMBURIO: Same objection.</p> <p>20 A. I believe so. I'm not for sure on this one</p> <p>21 product.</p> <p>22 Q. Okay. What's your understanding of what</p> <p>23 FiberSnare is as sold under AR-7209SN?</p> <p>24 A. No, I only understand -- I'm -- I'm familiar on</p> <p>25 the surface with this product, and I've seen different</p>	<p>124</p> <p>1 122 -- Exhibit 122?</p> <p>2 MR. TAMBURIO: Object to form. And it</p> <p>3 mischaracterizes the exhibit.</p> <p>4 A. Yes.</p> <p>5 Q. Does the No. 5 FiberWire sold with AR-7219 have</p> <p>6 the same structure and configuration as the suture shown</p> <p>7 in Exhibit 122?</p> <p>8 MR. TAMBURIO: Same objection.</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Does the No. 5 TigerWire shown or sold</p> <p>11 with AR-7219 have the same structure and configuration as</p> <p>12 the No. 2 TigerWire in Exhibit 126?</p> <p>13 MR. TAMBURIO: Object to form.</p> <p>14 A. Yes.</p> <p>15 Q. And the No. 2 FiberWire sold under AR-7219, does</p> <p>16 that have the same structure and configuration as the No.</p> <p>17 2 FiberWire shown in Exhibit 122?</p> <p>18 MR. TAMBURIO: Same objection.</p> <p>19 A. Sorry. Did you say FiberWire?</p> <p>20 Q. Yeah. Do you want me to repeat it?</p> <p>21 A. Please.</p> <p>22 Q. Okay. And the No. 2 FiberWire sold under</p> <p>23 AR-7219, does that have the same structure and</p> <p>24 configuration as the No. 2 FiberWire shown in Exhibit 122?</p> <p>25 MR. TAMBURIO: Same objection.</p>
<p>123</p> <p>1 appearances of it, so I can't answer for sure. It doesn't</p> <p>2 appear -- I've seen it in appearance it looked a little</p> <p>3 different, so I don't want to answer --</p> <p>4 Q. Okay.</p> <p>5 A. -- incorrectly.</p> <p>6 Q. Okay. Does the No. 2 TigerStick of AR-7209T the</p> <p>7 same -- have the same structure and configuration as the</p> <p>8 No. 2 FiberWire in Exhibit 126?</p> <p>9 MR. TAMBURIO: Object to form.</p> <p>10 A. Yes.</p> <p>11 Q. Do you understand what I'm saying when I say</p> <p>12 structure and configuration?</p> <p>13 A. Yes, I interpret it as approximately the same</p> <p>14 makeup.</p> <p>15 Q. As that shown?</p> <p>16 A. As that shown.</p> <p>17 Q. Okay. Does the No. 5 FiberWire AR-7210 have the</p> <p>18 same structure -- Strike that.</p> <p>19 Does the No. 5 FiberWire in AR-7210 have the same</p> <p>20 structure and configuration as the No. 5 FiberWire shown</p> <p>21 in Exhibit 122?</p> <p>22 MR. TAMBURIO: Objection to form.</p> <p>23 A. Yes.</p> <p>24 Q. And does the No. 5 FiberWire AR-7211 have the</p> <p>25 same structure and configuration as the FiberWire shown in</p>	<p>125</p> <p>1 A. Yes.</p> <p>2 Q. And the No. 2 FiberWire sold under AR-7220 and</p> <p>3 AR-7221, do they have the same structure and configuration</p> <p>4 as the 2-0 suture shown in Exhibit 121?</p> <p>5 MR. TAMBURIO: Object to form.</p> <p>6 A. Yes.</p> <p>7 Q. And the No. 2 -- excuse me. Does the 2-0</p> <p>8 FiberStick have the same structure -- Strike that.</p> <p>9 Does the 2-0 FiberStick in AR-7222 have the same</p> <p>10 structure and configuration as the 2-0 FiberWire shown in</p> <p>11 Exhibit 121?</p> <p>12 MR. TAMBURIO: Same objection.</p> <p>13 A. Yes.</p> <p>14 Q. Does the 3-0 FiberWire in AR-7225 and AR-7227-01</p> <p>15 and -02 have the same structure and configuration as the</p> <p>16 3-0 FiberWire shown in Exhibit 124?</p> <p>17 MR. TAMBURIO: Same objection.</p> <p>18 A. Yes.</p> <p>19 Q. Does the 4-0 FiberWire sold under AR-7228,</p> <p>20 7230-01, and 7230-02 have the same structure and</p> <p>21 configuration as the 4-0 FiberWire suture in Exhibit 125?</p> <p>22 MR. TAMBURIO: Same objection.</p> <p>23 A. Yes.</p> <p>24 Q. Does the 4-0 FiberLoop in AR-7229-12 and</p> <p>25 AR-7229-20 have the same structure and configuration as</p>

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS

3 DePuy Mitek, Inc., a
4 Massachusetts Corporation,

5 Plaintiff,

6 vs.

CIVIL ACTION
NO. 04-12457 PBS

7 Arthrex, Inc., a Delaware
8 Corporation,

9 Defendant.

10 CONTINUATION
11 DEPOSITION OF:

PETER DREYFUSS

12 DATE:

December 7, 2005

13 TIME:

8:03 a.m. to 1:21 p.m.

14 LOCATION:

The Staybridge Suites
4805 Tamiami Trail North
Naples, FL

16 TAKEN BY:

Plaintiff

17 REPORTER:

Deborah A. Krotz, RPR, CRR

18 VIDEOGRAPHER:

Michael Sturdevant, CLVS

74

1 Q. And if you see in the second paragraph, second
2 sentence, it says, "The Black/White Suture commonly known
3 as TigerWire has a blend of nylon and the ultra high
4 molecular weight polyethylene." Do you see that?

5 A. Yes.

6 Q. And if you skip a sentence, it says, "In place of
7 the nylon, a silk suture will be used." Do you see that?

8 A. Yes, I do.

9 Q. Is the only difference between Arthrex's
10 TigerWire and Arthrex's FiberWire with silk is the silk
11 suture is used in place of the nylon marker strand in
12 Arthrex's TigerWire product; is that right?

13 MR. SABER: Object; vague and confusing question.

14 Q. Do you understand the question?

15 A. I understand, I believe, from what I read here
16 that that is true.

17 Q. And the last time we were here, you described the
18 design and construction of the TigerWire product. Do you
19 remember that?

20 A. Yes, I understand that.

21 Q. What is the purpose of the nylon marking strand
22 in Arthrex's TigerWire product?

23 A. Identification. Visual identification.

24 Q. Is there any other purpose to the nylon marking
25 strand in Arthrex's TigerWire product?

75

1 A. That's the primary purpose. I'm not sure if
2 there's secondary purposes, per se.

3 Q. Does the introduction of a nylon marking strand
4 in the TigerWire product affect any of the physical
5 characteristics of the TigerWire product?

6 A. Affect in --

7 Q. Other than the visual distinction that you can
8 see with the introduction of a nylon marking strand, does
9 the nylon marking strand in TigerWire affect any other
10 characteristic of the braided suture?

11 A. Yes.

12 Q. What is -- what?

13 A. Minute differences in its feel and strength,
14 characteristics.

15 Q. But you would describe them as minute
16 differences?

17 A. Not enough to cause it not to become a product.

18 Q. Can you explain that?

19 A. It's --

20 Q. In other words, the introduction of the nylon
21 marking strand doesn't affect any of the marketing
22 qualities or engineering qualities that make FiberWire
23 FiberWire; does that make sense?

24 MR. SABER: Objection; vague.

25 A. It -- They are comparable.

76

1 Q. But they show -- But a No. 2 TigerWire, for
2 instance, and a No. 2 FiberWire show very similar knot
3 strength, tensile strength, handleability, and what not,
4 all of the characteristics that define FiberWire?

5 A. I believe so.

6 Q. Okay. And is that true also with the
7 introduction of silk rather than a nylon marker?

8 A. I don't know.

9 Q. Do you know whether the silk used in the
10 FiberWire with silk suture affects any of the
11 characteristics of the suture?

12 A. No, I don't.

13 Q. Based on your understanding of Arthrex's
14 FiberWire with silk product, do you think you would be
15 able to draw a cross-section of the suture?

16 A. I -- No.

17 Q. No? But as far as you know, the only difference
18 between the TigerWire and a FiberWire with silk is instead
19 of the nylon, it's a piece of silk?

20 A. That would be a good generalization.

21 Q. Okay. And Don Grafton would know this
22 information?

23 A. I believe so, yes.

24 (DePuy Mitek Exhibit No. 142, Design History File
25 for FiberWire 3-0 and 4-0, ARM 6580 through 6950, was

77

1 marked for identification.)

2 Q. I'm going to hand you a document labeled DePuy
3 Mitek Exhibit 142. It's a document with Bates numbers ARM
4 6580 through 6950.

5 Have you seen Exhibit 142 before?

6 A. I believe so.

7 Q. And what is DePuy Mitek Exhibit 142?

8 A. The Design History File for FiberWire new sizes
9 -- new sizes of FiberWire.

10 Q. And what new sizes for FiberWire?

11 A. 3-0 and 4-0.

12 Q. Do you have any reason to believe the information
13 in Exhibit 142 is inaccurate?

14 MR. SABER: Objection; overbroad.

15 A. No, I don't.

16 MR. FALKE: I'm just trying to authenticate the
17 document.

18 MR. SABER: No, I have no problem with you
19 authenticating the document, but I -- you know -- this
20 is, again, a document of hundreds of pages. And to
21 ask him to -- a generalized question like that I think
22 is kind of unfair.

23 BY MR. FALKE:

24 Q. Do the instructions for use that are included
25 with all of Arthrex's FiberWire product indicate that the

BROOKSTEIN DECLARATION EXHIBIT 9



sp 154

BTH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511

Art Unit: 1504

Filed : February 19, 1992

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

December 2, 1992

(Date of Deposit)

Matthew S. Goodwin

Name of applicant, assignee, or Registered Representative

(Signature)

December 2, 1992

(Date of Signature)

1500

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS

DMI000618

The braided suture is made up of multifilament yarns. A multifilament yarn is a bundle of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be bundled to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct intertwining contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a multifilament yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a structured mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilaments yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a random, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Dodd"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56).

However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The only component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the essence of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches randomized braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a structured braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

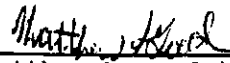
3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.

5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,


Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2794
December 2, 1992

BROOKSTEIN DECLARATION EXHIBIT 10

Marks' **Standard Handbook for Mechanical Engineers**

Revised by a staff of specialists

THEODORE BAUMEISTER *Editor-in-Chief*

*Stevens Professor Emeritus of Mechanical Engineering,
Columbia University in the City of New York*

EUGENE A. AVALLONE *Associate Editor*

*Consulting Engineer; Professor of Mechanical Engineering,
The City College of the City University of New York*

THEODORE BAUMEISTER III *Associate Editor*

*Consultant, Information Systems Department,
E. I. du Pont de Nemours & Co.*

Eighth Edition

McGRAW-HILL BOOK COMPANY

New York St. Louis San Francisco Auckland Bogotá
Düsseldorf Johannesburg London Madrid
Mexico Montreal New Delhi Panama
Paris São Paulo Singapore
Sydney Tokyo Toronto

Library of Congress Cataloged The First Issue
of this title as follows:

Standard handbook for mechanical engineers. 1st-- ed.;
1916--

New York, McGraw-Hill.

v. Illus. 18--24 cm.

Title varies: 1916--58: Mechanical engineers' handbook.

Editors: 1916--51, L. S. Marks.--1958-- T. Baumeister.

Includes bibliographies.

1. Mechanical engineering--Handbooks, manuals, etc. I. Marks,
Lionel Simeon, 1871-- ed. II. Baumeister, Theodore, 1897--
ed. III. Title: Mechanical engineers' handbook.

TJ151.S82 502'.4'621 16--12915

Library of Congress [r68z*60--2]

ISBN 0-07-004123-7

MARKS' STANDARD HANDBOOK FOR MECHANICAL ENGINEERS

Copyright © 1978, 1967, 1958 by McGraw-Hill, Inc. All Rights Reserved.

Copyright renewed 1979 by Lionel P. Marks and Alison P. Marks.

Copyright renewed 1952 by Lionel S. Marks. Copyright renewed 1969, 1958 by Lionel
Peabody Marks.

Copyright 1951, 1941, 1930, 1924, 1916 by McGraw-Hill, Inc. All Rights Reserved.

Printed in the United States of America. No part of this publication may be repro-
duced, stored in a retrieval system, or transmitted, in any form or by any means,
electronic, mechanical, photocopying, recording, or otherwise, without the prior
written permission of the publisher.

67891011 KPKP 87654321

First Edition	Third Edition	Fifth Edition	Seventh Edition
<i>Eleven Printings</i>	<i>Seven Printings</i>	<i>Seven Printings</i>	<i>Fifteen Printings</i>
Second Edition	Fourth Edition	Sixth Edition	
<i>Seven Printings</i>	<i>Thirteen Printings</i>	<i>Eight Printings</i>	

*The editors for this book were Harold B. Crawford and Lester Strong
and the production supervisor was Teresa F. Leaden.
It was set in Janson by University Graphics, Inc.*

Printed and bound by Kingsport Press, Inc.

*The editors and the publishers will be grateful to readers who notify them
of any inaccuracy or important omission in this book*

Table 1. Fiber Properties*

Kind	Source	Length of fiber, in.	Width or diam of cells, microns	Specific gravity	Moisture regain,† percent	Chemical description	Principal uses
Cotton.....	Plant seed hair	5/8-2	8-27	1.52	8.5	Cellulose	Industrial, household, apparel
Jute†.....	Plant bast	50-80	15-20	1.48	13.7	Lignocellulose	Bagging, twine, carpet backing
Wool.....	Animal	2-16	10-50	1.32	17	Protein	Apparel, household, industrial
Viscose.....	Manufactured	Any	8-43	1.52	11	Regenerated cellulose	Apparel, industrial, household
Cellulose acetate	Manufactured	Any	12-46	1.33	6	Cellulose ester	Apparel, industrial, household
Nylon.....	Manufactured	Any	8	1.14	4.2	Polyamide	Apparel, industrial, household
Casein.....	Manufactured	Any	11-28	1.3	4.1	Protein	Apparel
Flax†.....	Plant bast	12-36	15-17	1.5	12	Cellulose	Household, apparel, industrial
Hemp†.....	Plant bast	18-23	1.48	12	Cellulose	Twine, halyards, rigging
Sisal†.....	Plant leaf	30-48	10-30	Lignocellulose	Twine, cordage
Manila†.....	Plant leaf	60-140	10-30	Lignocellulose	Rope, twine, cordage
Ramie†.....	Plant bast	3-10	24-70	1.52	Cellulose	Household, apparel, seines
Silk.....	Silkworm	Any	5-23	1.35	11	Protein	Apparel, household, industrial
Glass.....	Manufactured	Any	3	2.5	0	Fused metal oxides	Industrial, household
Dacron.....	Manufactured	Any	8	1.38	0.4	Polyester	Apparel, industrial, household

1 in = 0.0254 m; $1\mu = 10^{-6}$ m. The more up-to-date term for the micron (μ) is the micrometer (μm).

*Adapted from Smith, Textile Fibers, *Proc. ASTM*, 1944; Appel, A Survey of the Synthetic Fibers, *Am. Dyestuff Reporter*, 34, 1945, pp. 21-26; and other sources.

†These fibers are commercially used as bundles of cells. They vary greatly in width. Width figures given are for the individual cells.

‡In air at 70°F and 65 percent relative humidity.

Table 2. Tensile Properties of Single Fibers*

Fiber	Breaking tenacity, gpd	Extension at break, percent	Elastic recovery at corresponding strain, percent	Elastic modulus,† gpd
Glass.....	6.0-7.3	3.0-4.0	100 at 2.9	200-300
Fortisan (rayon).....	6.0-7.0	6	100 at 1.2	150-200
			60 at 2.4	
Flax.....	2.6-7.7	2.7-3.3	65 at 2	
Nylon 6, 6.....	4.6-9.2	16-32	100 at 8	25-50
Nylon 6.....	4.5-8.6	16-40	100 at 8	25-50
Silk.....	2.4-5.1	10-25	92 at 2	75-125
Saran.....	1.1-2.3	15-25	95 at 10	
Cotton.....	3.0-4.9	3-7	74 at 2	50-100
Steel (90,000 psi T.S.).....	0.9	28	300
Steel (music wire).....	3.5	8	300
Viscose rayon.....	1.5-5.0	15-30	82 at 2	50-150
Wool.....	1.0-1.7	25-35	99 at 2	25-40
Acetate rayon.....	1.3-1.5	23-34	100 at 1	25-40
Polyester.....	4.4-7.8	10-25	100 at 2	50-80
Polypropylene.....	4.0-7.0	15-25	95 at 7	15-50
Polytetrafluoroethylene.....	1.7	13	

*From Kaswell, "Wellington Sears Handbook of Industrial Textiles," Wellington Sears Co., Inc.

†From Kaswell, "Textile Fibers, Yarns, and Fabrics." Reinhold.

BROOKSTEIN DECLARATION EXHIBIT 11

United States Patent [19][11] **4,413,110****Kavesh et al.**[45] **Nov. 1, 1983**

[54] **HIGH TENACITY, HIGH MODULUS
POLYETHYLENE AND POLYPROPYLENE
FIBERS AND INTERMEDIATES
THEREFORE**

[75] Inventors: **Sheldon Kavesh, Whippany; Dusan C.
Prevorsek, Morristown, both of N.J.**

[73] Assignee: **Allied Corporation, Morris
Township, Morris County, N.J.**

[21] Appl. No.: **359,019**

[22] Filed: **Mar. 19, 1982**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 259,266, Apr. 30,
1981, abandoned.

[51] Int. Cl.³ **C08F 10/02; C08F 10/06;
D01F 6/04; D01F 6/06**

[52] U.S. Cl. **526/348.1; 264/164;
264/205; 264/210.8; 524/108; 524/366;
524/462; 524/464; 524/583; 524/585; 526/351;
526/352**

[58] Field of Search **526/348.1, 351, 352**

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,137,394 1/1979 Meihuizen et al. 528/502

FOREIGN PATENT DOCUMENTS

3004699 8/1980 Fed. Rep. of Germany .
2051667 1/1981 United Kingdom .

OTHER PUBLICATIONS

Smith et al., "Ultrahigh-Strength Polyethylene Filaments by Solution Spinning and Hot Drawing", *Polymer Bulletin*, vol. 1, pp. 733-736, (1979).
Cansfield et al., "The Preparation of Ultra-High Modulus Polypropylene Films and Fibres", *Polymer Eng. & Sci.*, vol. 16, No. 11, pp. 721-724, (1976).
Kalb & Pennings, "Hot Drawing of Porous High Molecular Weight Polyethylene", *Polymer Bulletin*, vol. 1, pp. 879-880, (1979).
Kalb & Pennings, "Maximum Strength and Drawing

Mechanism of Hot Drawn High Molecular Weight Polyethylene", *J. Mat. Sci.*, vol. 15, pp. 2584-2590, (1980).

Imada et al., "Crystal Orientation and Some Properties of Solid-State Extrudate of Linear Polyethylene", *J. Mat. Sci.* 6, (1971), 537-546.

Smith et al., "Ultradrawing of High-Molecular-Weight Polyethylene Cast From Solution", *J. Pol. Sci.*, 19, 877-888, (1981).

Smith et al., "Ultrahigh-Strength Polyethylene Filaments . . .", *Makromol. Chem.*, 180, 2983-2986, (1979).
Kalb et al., "Spinning of High Molecular Weight Polyethylene . . .", *Polymer Bulletin* 1, 871-876, (1979).

Smith et al., "Ultra-High-Strength Polyethylene . . .", *J. Mat. Sci.* 15, (1980), 505-514.

Kalb & Pennings, "Hot Drawing of Porous High Molecular Weight Polyethylene", *Polymer* 21, (1), 3-4, (1980).

Smook et al., "Influence of Spinning/Hot Drawing Conditions on the Tensile Strength of Porous High Molecular Weight Polyethylene", *Polymer Bulletin*, vol. 2, pp. 775-783, (1980).

Primary Examiner—Stanford M. Levin

Attorney, Agent, or Firm—Alan M. Doernberg; Gerhard H. Fuchs; Roy H. Massengill

[57] **ABSTRACT**

Solutions of ultrahigh molecular weight polymers such as polyethylene in a relatively non-volatile solvent are extruded through an aperture at constant concentration through the aperture and cooled to form a first gel of indefinite length. The first gels are extracted with a volatile solvent to form a second gel and the second gel is dried to form a low porosity xerogel. The first gel, second gel or xerogel, or a combination, are stretched. Among the products obtainable are polyethylene fibers of greater than 30 or even 40 g/denier tenacity and of modulus greater than 1000 or even 1600 or 2000 g/denier.

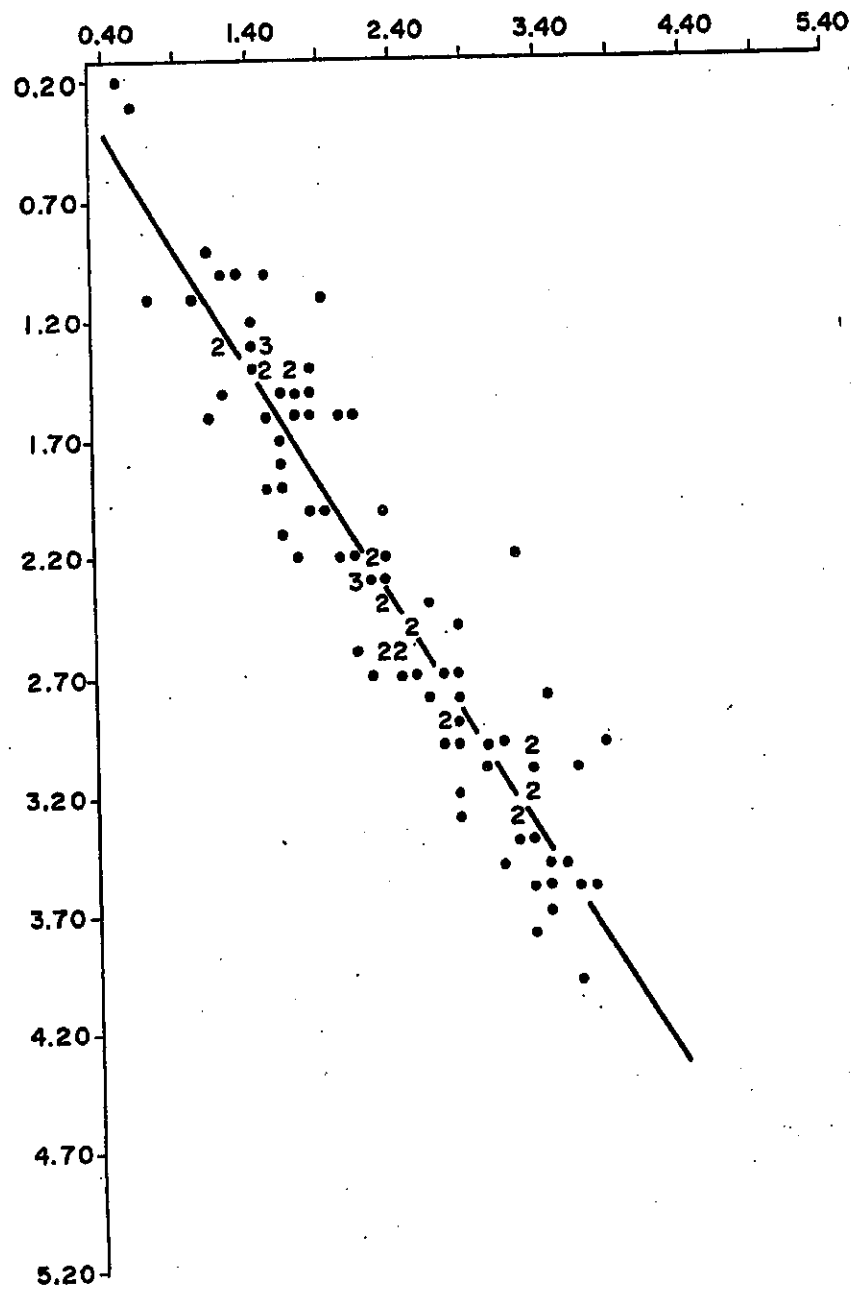
19 Claims, 7 Drawing Figures

U.S. Patent Nov. 1, 1983

Sheet 1 of 7

4,413,110

FIG. 1



U.S. Patent

Nov. 1, 1983

Sheet 2 of 7

4,413,110

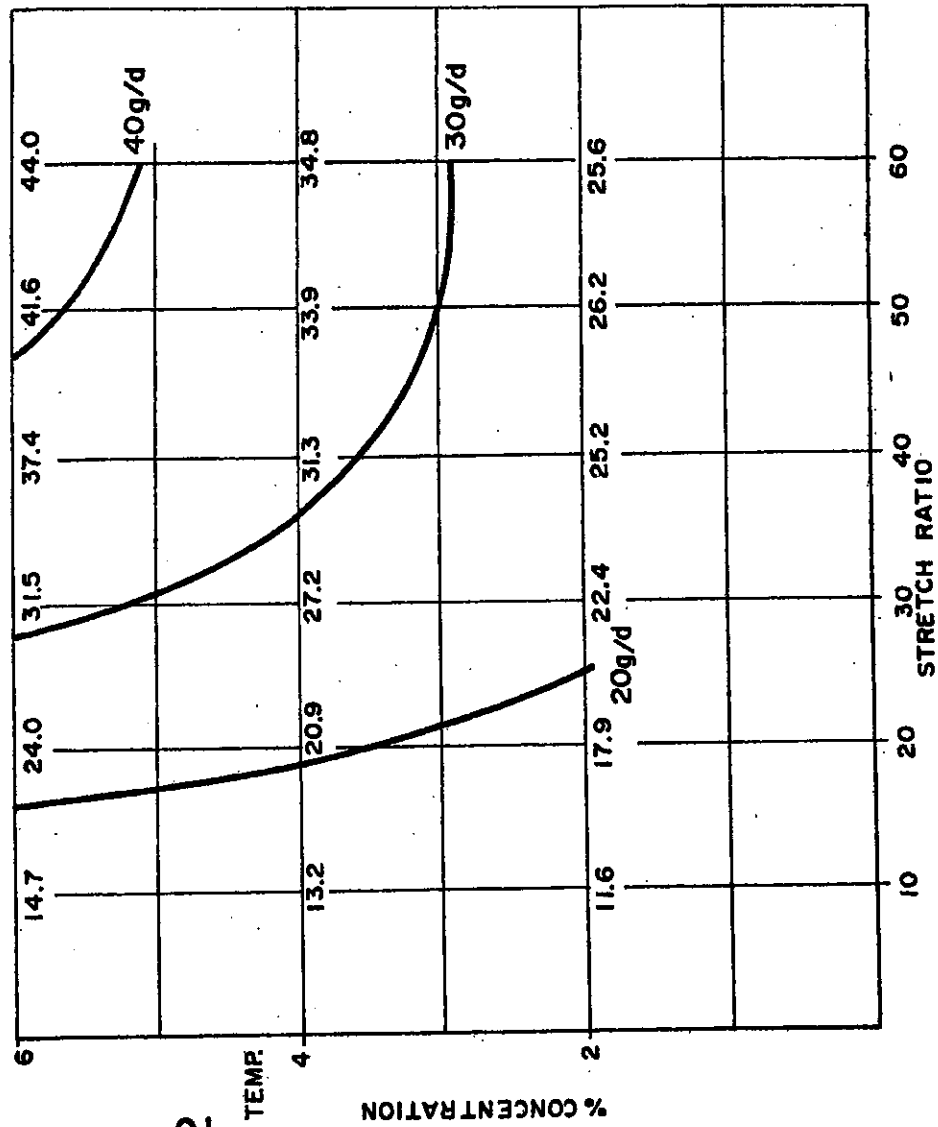


FIG. 2

140°C = STRETCH TEMP
24 IV PE

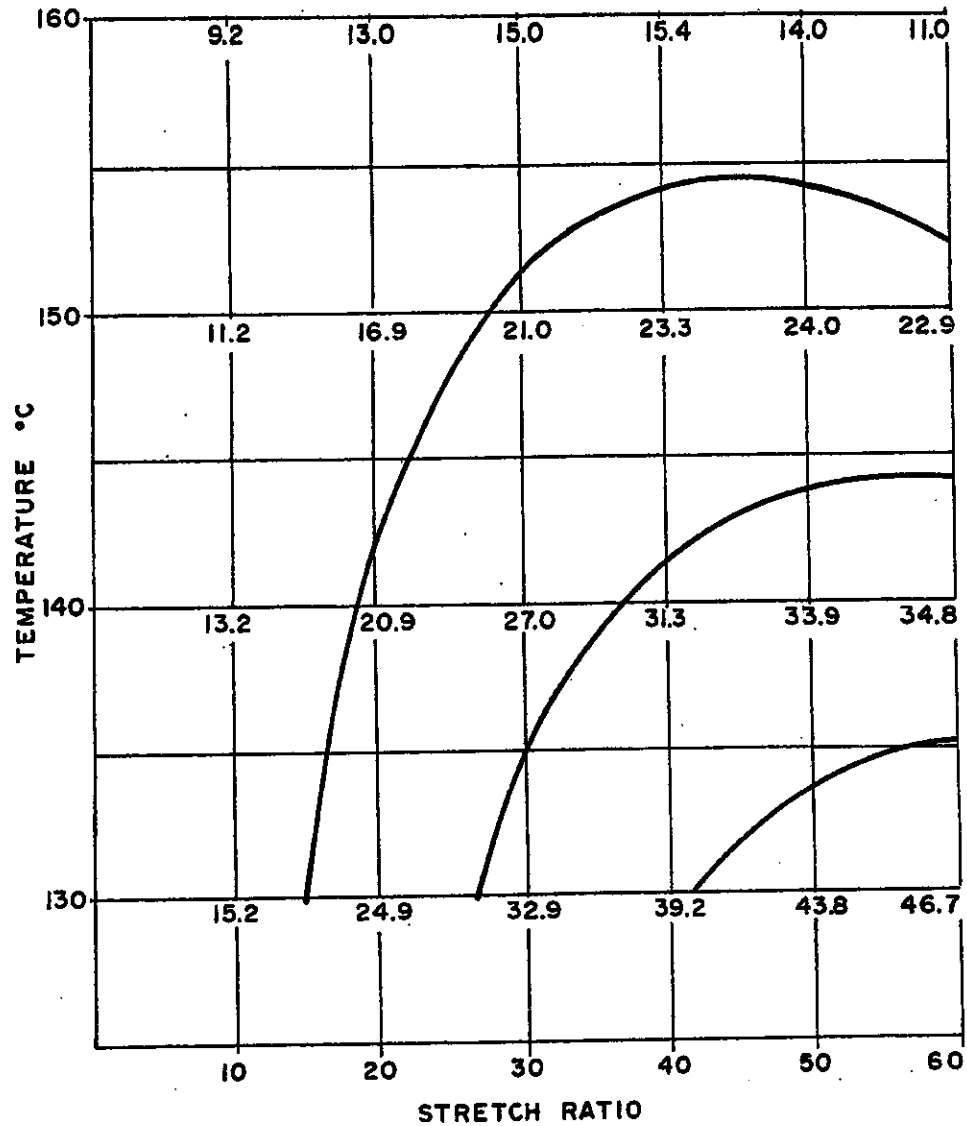
U.S. Patent Nov. 1, 1983

Sheet 3 of 7

4,413,110

FIG. 3

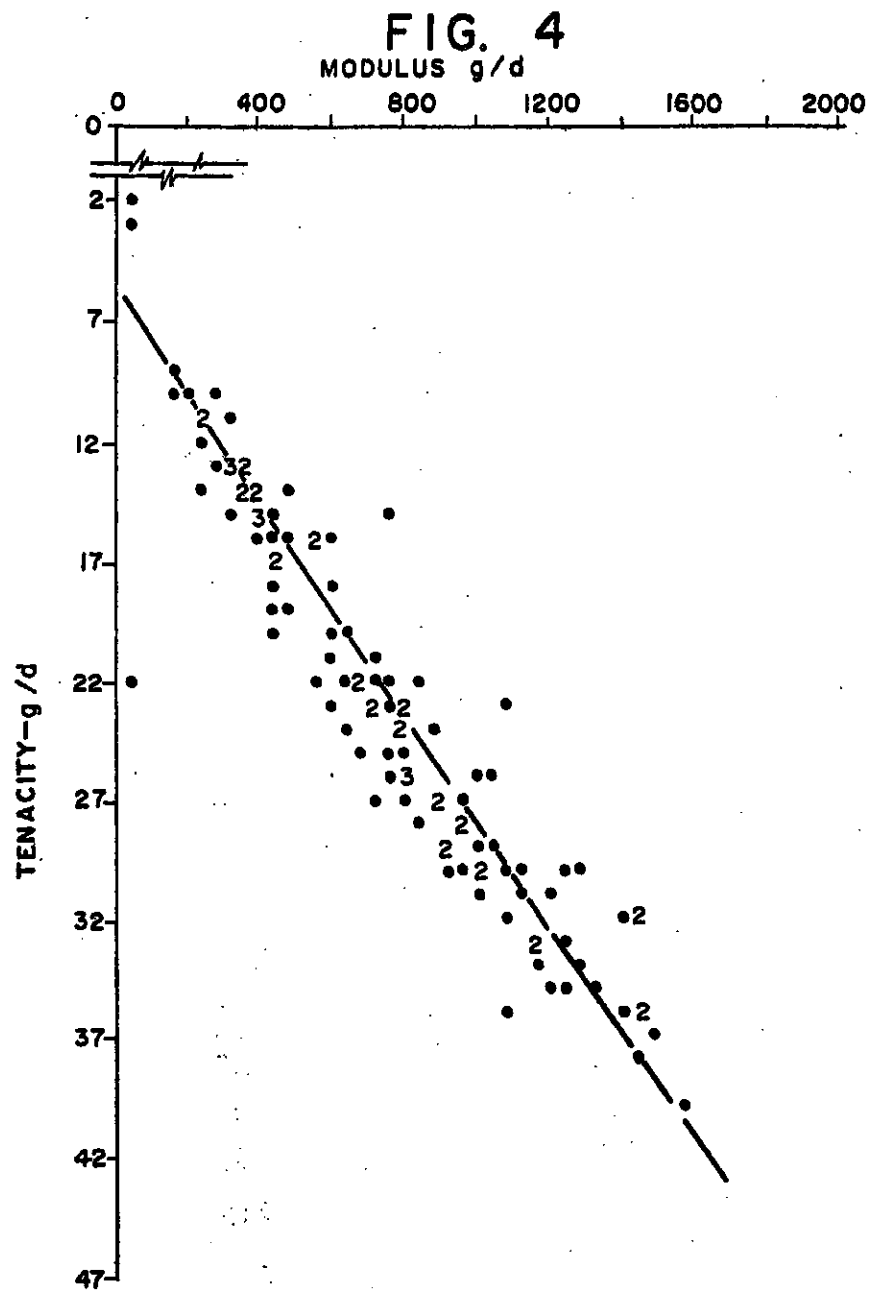
4% GEL CONCENTRATION
24 IV



U.S. Patent Nov. 1, 1983

Sheet 4 of 7

4,413,110



4,413,110

1

HIGH TENACITY, HIGH MODULUS POLYETHYLENE AND POLYPROPYLENE FIBERS AND INTERMEDIATES THEREFORE

DESCRIPTION

This is a continuation-in-part of Ser. No. 259,266, filed Apr. 30, 1981, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to ultrahigh molecular weight polyethylene and polypropylene fibers having high tenacity, modulus and toughness values and a process for their production which includes a gel intermediate.

The preparation of high strength, high modulus polyethylene fibers by growth from dilute solution has been described by U.S. Pat. No. 4,137,394 to Meihuizen et al. (1979) and pending application Ser. No. 225,288 filed Jan. 15, 1981, now U.S. Pat. No. 4,356,138.

Alternative methods to the preparation of high strength fibers have been described in various recent publications of P. Smith, A. J. Pennings and their co-workers. German Off. No. 3004699 to Smith et al. (Aug. 21, 1980) describes a process in which polyethylene is first dissolves in a volatile solvent, the solution is spun and cooled to form a gel filament, and finally the gel filament is simultaneously stretched and dried to form the desired fiber.

UK Patent application GB No. 2,051,667 to P. Smith and P. J. Lemstra (Jan. 21, 1981) discloses a process in which a solution of the polymer is spun and the filaments are drawn at a stretch ratio which is related to the polymer molecular weight, at a drawing temperature such that at the draw ratio used the modulus of the filaments is at least 20 GPa. The application notes that to obtain the high modulus values required, drawing must be performed below the melting point of the polyethylene. The drawing temperature is in general at most 135° C.

Kalb and Pennings in Polymer Bulletin, vol. 1, pp. 879-80 (1979), J. Mat. Sci., vol. 15, 2584-90 (1980) and Smook et al. in Polymer Bull., vol. 2, pp. 775-83 (1980) describe a process in which the polyethylene is dissolved in a nonvolatile solvent (paraffin oil) and the solution is cooled to room temperature to form a gel. The gel is cut into pieces, fed to an extruder and spun into a gel filament. The gel filament is extracted with hexane to remove the paraffin oil, vacuum dried and the stretched to form the desired fiber.

In the process described by Smook et. al. and Kalb and Pennings, the filaments were non-uniform, were of high porosity and could not be stretched continuously to prepare fibers of indefinite length.

BRIEF DESCRIPTION OF THE INVENTION

The present invention includes a stretched polyethylene fiber of substantially indefinite length being of weight average molecular weight at least about 500,000 and having a tenacity of at least about 20 g/denier, a tensile modulus at least about 500 g/denier, a creep value no more than about 5% (when measured at 10% of breaking load for 50 days at 23° C.), a porosity less than about 10% and a melting temperature of at least about 147° C. measured at 10° C./minute heating rate by differential scanning calorimetry).

The present invention also includes a stretched polyethylene fiber of substantially indefinite length being of

2

weight average molecular weight of at least about 1,000,000 and having a tensile modulus of at least about 1600 g/denier, a main melting point of at least about 147° C. (measured at 10° C./minute heating rate by differential scanning calorimetry) and an elongation-to-break of not more than 5%.

The present invention also includes a stretched polypropylene fiber of substantially indefinite length being of weight average molecular weight of at least about 750,000 and having a tenacity of at least about 8 g/denier, a tensile modulus of at least about 160 g/denier and a main melting temperature of at least about 168° C. (measured at 10° C./minute heating rate by differential scanning calorimetry)

The present invention also includes a polyolefin gel fiber of substantially indefinite length comprising between about 4 and about 20 weight % solid polyethylene of weight average molecular weight at least about 500,000 or solid polypropylene of weight average molecular weight at least about 750,000, and between about 80 and about 96 weight % of a swelling solvent miscible with high boiling hydrocarbon and having an atmospheric boiling point less than about 50° C.

The preferred method of preparing the novel polyethylene and polypropylene fibers of the present invention is via the novel polyolefin gel fiber of the invention and, more preferably, also via a novel xerogel fiber, by a process claimed in out copending, commonly assigned application Ser. No. 539,020, filed herewith.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graphic view of the tenacities of polyethylene fibers prepared according to Examples 3-99 of the present invention versus calculated values therefore as indicated in the Examples. The numbers indicate multiple points.

FIG. 2 is a graphic view of the calculated tenacities of polyethylene fibers prepared according to Examples 3-99 as a function of polymer concentration and draw ratio at a constant temperature of 140° C.

FIG. 3 is a graphic view of the calculated tenacities of polyethylene fibers prepared according to Examples 3-99 as a function of draw temperature and draw (or stretch) ratio at a constant polymer concentration of 4%.

FIG. 4 is a graphic view of tenacity plotted against tensile modulus for polyethylene fibers prepared in accordance with Examples 3-99.

FIG. 5 is a schematic view of a first process used to prepare the products of the present invention.

FIG. 6 is a schematic view of a second process used to prepare the products of the present invention.

FIG. 7 is a schematic view of a third process used to prepare the products of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

There are many applications which require a load bearing element of high strength, modulus, toughness, dimensional and hydrolytic stability and high resistance to creep under sustained loads.

For example, marine ropes and cables, such as the mooring lines used to secure supertankers to loading stations and the cables used to secure deep sea drilling platforms to underwater anchorage, are presently constructed of materials such as nylon, polyester, aramids and steel which are subject to hydrolytic or corrosive

3

4,413,110

attack by sea water. In consequence such mooring lines and cables are constructed with significant safety factors and are replaced frequently. The greatly increased weight and the need for frequent replacement create substantial operational and economic burdens.

The fibers and films of this invention are of high strength, extraordinarily high modulus and great toughness. They are dimensionally and hydrolytically stable and resistant to creep under sustained loads.

The fibers and films of the invention prepared according to the present process possess these properties in a heretofore unattained combination, and are therefore quite novel and useful materials.

Other applications for the fibers and films of this invention include reinforcements in thermoplastics, thermosetting resins, elastomers and concrete for uses such as pressure vessels, hoses, power transmission belts, sports and automotive equipment, and building construction.

In comparison to the prior art fibers prepared by Smith, Lemstra and Pennings described in Off No. 30 04 699, GB No. 205,1667 and other cited references, the strongest fibers of the present invention are of higher melting point, higher tenacity and much higher modulus. Additionally, they are more uniform, and less porous than the prior art fibers.

In comparison with Off No. 30 04 699 to Smith et. al. the process of the present invention has the advantage of greater controllability and reliability in that the steps of drying and stretching may be separate and each step may be carried out under optimal conditions. To illustrate, Smith & Lemstra in Polymer Bulletin, vol. 1, pp. 733-36 (1979) indicate that drawing temperature, below 143° C., had no effect on the relationships between either tenacity or modulus and stretch ratio. As will be seen, the properties of the fibers of the present invention may be controlled in part by varying stretch temperature with other factors held constant.

In comparison with the procedures described by Smook et. al in Polymer Bulletin, vol. 2, pp. 775-83 (1980) and in the above Kalb and Pennings articles, the process of the present invention has the advantage that the intermediate gel fibers which are spun are of uniform concentration and this concentration is the same as the polymer solution as prepared. The advantages of this uniformity are illustrated by the fact that the fibers of the present invention may be stretched in a continuous operation to prepare packages of indefinite length. Additionally, the intermediate xerogel fibers of the present invention preferably contain less than about 10 volume % porosity compared to 23-65% porosity in the dry gel fibers described by Smook et. al. and Kalb and Pennings.

The crystallizable polymer used in the present invention may be polyethylene or polypropylene. In the case of polyethylene, suitable polymers have molecular weights (by intrinsic viscosity) in the range of about one to ten million. This corresponds to a weight average chain length of 3.6×10^4 to 3.6×10^5 monomer units or 7×10^4 to 7.1×10^5 carbons. Polypropylene should have similar backbone carbon chain lengths. The weight average molecular weight of polyethylene used is at least about 500,000 (6 IV), preferably at least about 1,000,000 (10 IV) and more preferably between about 2,000,000 (16 IV) and about 8,000,000 (42 IV). The weight average molecular weight of polypropylene used is at least about 750,000 (5 IV), preferably at least about 1,000,000 (6 IV), more preferably at least about

4

1,500,000 (9 IV), and most preferably between about 2,000,000 (11 IV) and about 8,000,000 (33 IV). The IV numbers represent intrinsic viscosity of the polymer in decalin at 135° C.

The first solvent should be non-volatile under the processing conditions. This is necessary in order to maintain essentially constant the concentration of solvent upstream and through the aperture (die) and to prevent non-uniformity in liquid content of the gel fiber or film containing first solvent. Preferably, the vapor pressure of the first solvent should be no more than about 20 kPa (about one-fifth of an atmosphere) at 175° C., or at the first temperature. Preferred first solvents for hydrocarbon polymers are aliphatic and aromatic hydrocarbons of the desired non-volatility and solubility for the polymer. The polymer may be present in the first solvent at a first concentration which is selected from a relatively narrow range, e.g. about 2 to 15 weight percent, preferably about 4 to 10 weight percent and more preferably about 5 to 8 weight percent; however, once chosen, the concentration should not vary adjacent the die or otherwise prior to cooling to the second temperature. The concentration should also remain reasonably constant over time (i.e. length of the fiber or film).

The first temperature is chosen to achieve complete dissolution of the polymer in the first solvent. The first temperature is the minimum temperature at any point between where the solution is formed and the die face, and must be greater than the gelation temperature for the polymer in the solvent at the first concentration. For polyethylene in paraffin oil at 5-15% concentration, the gelation temperature is approximately 100-130° C.; therefore, a preferred first temperature can be between 180° C. and 250° C., more preferably 200-240° C. While temperatures may vary above the first temperature at various points upstream of the die face, excessive temperatures causative of polymer degradation should be avoided. To assure complete solubility, a first temperature is chosen whereat the solubility of the polymer exceeds the first concentration, and is typically at least 100% greater. The second temperature is chosen whereas the solubility of the polymer is much less than the first concentration. Preferably, the solubility of the polymer in the first solvent at the second temperature is no more than 1% of the first concentration. Cooling of the extruded polymer solution from the first temperature to the second temperature should be accomplished at a rate sufficiently rapid to form a gel fiber which is of substantially the same polymer concentration as existed in the polymer solution. Preferably the rate at which the extruded polymer solution is cooled from the first temperature to the second temperature should be at least about 50° C. per minute.

Some stretching during cooling to the second temperature is not excluded from the present invention, but the total stretching during this stage should not normally exceed about 2:1, and preferably no more than about 1.5:1. As a result of those factors the gel fiber formed upon cooling to the second temperature consists of a continuous polymeric network highly swollen with solvent. The gel usually has regions of high and low polymer density on a microscopic level but is generally free of large (greater than 500 nm) regions void of solid polymer.

An aperture of circular cross section (or other cross section without a major axis in the plane perpendicular to the flow direction more than 8 times the smallest axis

in the same plane, such as oval, Y- or X-shaped aperture) is used so that both gels will be gel fibers, the xerogel will be an xerogel fiber and the product will be a fiber. The diameter of the aperture is not critical, with representative apertures being between about 0.25 mm and about 5 mm in diameter (or other major axis). The length of the aperture in the flow direction should normally be at least about 10 times the diameter of the aperture (or other similar major axis), preferably at least 15 times and more preferably at least 20 times the diameter (or other similar major axis).

The extraction with second solvent is conducted in a manner that replaces the first solvent in the gel with second solvent without significant changes in gel structure. Some swelling or shrinkage of the gel may occur, but preferably no substantial dissolution, coagulation or precipitation of the polymer occurs.

When the first solvent is a hydrocarbon, suitable second solvents include hydrocarbons, chlorinated hydrocarbons, chlorofluorinated hydrocarbons and others, such as pentane, hexane, heptane, toluene, methylene chloride, carbon tetrachloride, trichlorotrifluoroethane (TCTFE), diethyl ether and dioxane.

The most preferred second solvents are methylene chloride (B.P. 39.8° C.) and TCFE (B.P. 47.5° C.). Preferred second solvents are the non-flammable volatile solvents having an atmospheric boiling point below about 80° C., more preferably below about 70° C. and most preferably below about 50° C. Conditions of extraction should remove the first solvent to less than 1% of the total solvent in the gel.

A preferred combination of conditions is a first temperature between about 150° C. and about 250° C., a second temperature between about -40° C. and about 40° C. and a cooling rate between the first temperature and the second temperature at least about 50° C./minute. It is preferred that the first solvent be a hydrocarbon, when the polymer is a polyolefin such as ultrahigh molecular weight polyethylene. The first solvent should be substantially non-volatile, one measure of which is that its vapor pressure at the first temperature should be less than one-fifth atmosphere (20 kPa), and more preferably less than 2 kPa.

In choosing the first and second solvents, the primary desired difference relates to volatility as discussed above. It is also preferred that the polymers be less soluble in the second solvent at 40° C. than in the first solvent at 150° C.

Once the gel containing second solvent is formed, it is then dried under conditions where the second solvent is removed leaving the solid network of polymer substantially intact. By analogy to silica gels, the resultant material is called herein a "xerogel" meaning a solid matrix corresponding to the solid matrix of a wet gel, with the liquid replaced by gas (e.g. by an inert gas such as nitrogen or by air). The term "xerogel" is not intended to delineate any particular type of surface area, porosity or pore size.

A comparison of the xerogel fibers of the present invention with corresponding dried gel fibers prepared according to prior art indicates the following major differences in structure: The dried xerogel fibers of the present invention preferably contain less than about ten volume percent pores compared to about 55 volume percent pores in the Kalb and Pennings dried gel fibers and about 23-65 volume percent pores in the Smook et al. dried gel fibers. The dried xerogel fibers of the present invention show a surface area (by the B.E.T. tech-

nique) of less than about 1 m²/g as compared to 28.8 m²/g in a fiber prepared by the prior art method (see Comparative Example 1 and Example 2, below).

The xerogel fibers of the present invention are also novel compared to dry, unstretched fibers of GB No. 2,051,667 and Off. 3004699 and related articles by Smith and Lemstra. This difference is evidenced by the deleterious effect of stretching below 75° C. or above 135° C. upon the Smith and Lemstra unstretched fibers. In comparison, stretching of the present xerogel fibers at room temperature and above 135° C. has beneficial rather than deleterious effects (see, for example, Examples 540-542, below). While the physical nature of these differences are not clear because of lack of information about Smith and Lemstra's unstretched fibers, it appears that one or more of the following characteristics of the present xerogel fibers must be lacking in Smith and Lemstra's unstretched fibers: (1) a crystalline orientation function less than 0.2, and preferably less than 0.1 as measured by wide angle X-ray diffraction; (2) microporosity less than 10% and preferably less than 3%; (3) a crystallinity index as measured by wide angle X-ray diffraction (see P. H. Hermans and A. Weidinger, *Macromol. Chem.* vol. 44, p. 24 (1961)) less than 80% and preferably less than 75% (4) no detectable fraction of the triclinic crystalline form and (5) a fractional variation in spherulite size across a diameter of the fiber less than 0.25.

Stretching may be performed upon the gel fiber after cooling to the second temperature or during or after extraction. Alternatively, stretching of the xerogel fiber may be conducted, or a combination of gel stretch and xerogel stretch may be performed. The stretching may be conducted in a single stage or it may be conducted in two or more stages. The first stage stretching may be conducted at room temperatures or at an elevated temperature. Preferably the stretching is conducted in two or more stages with the last of the stages performed at a temperature between about 120° C. and 160° C. Most preferably the stretching is conducted in at least two stages with the last of the stages performed at a temperature between about 135° C. and 150° C. The Examples, and especially Examples 3-99 and 111-486, illustrate how the stretch ratios can be related to obtaining particular fiber properties.

The product polyethylene fibers produced by the present process represent novel articles in that they include fibers with a unique combination of properties: a tensile modulus at least about 500 g/denier (preferably at least about 1000 g/denier, more preferably at least about 1600 g/denier and most preferably at least about 2000 g/denier), a tenacity at least about 20 g/denier (preferably at least about 30 g/denier and more preferably at least about 40 g/denier), a main melting temperature (measured at 10° C./minute heating rate by differential scanning calorimetry) of at least about 147° C. (preferably at least about 149° C.), a porosity of no more than about 10% (preferably no more than about 6% and more preferably no more than about 3%) and a creep value no more than about 5% (preferably no more than about 3%) when measured at 10% of breaking load for 50 days at 23° C. Preferably the fiber has an elongation to break at most about 7%, and more preferably not more than about 5% (which correlates with the preferred tensile modulus of at least about 1000 g/denier). In addition, the fibers have high toughness and uniformity. Furthermore, as indicated in Examples 3-99 and 111-489 below, trade-offs between various properties

4,413,110

7

can be made in a controlled fashion with the present process.

The novel polypropylene fibers of the present invention also include a unique combination of properties, previously unachieved for polypropylene fibers: a tenacity of at least about 8 g/denier (preferably at least about 11 g/denier and more preferably at least about 13 g/denier), a tensile modulus at least about 160 g/denier (preferably at least about 200 g/denier and more preferably at least about 220 g/denier), a main melting temperature (measured at 10° C./minute heating rate by differential scanning calorimetry) at least about 168° C. (preferably at least about 170° C.) and a porosity less about 10% (preferably no more than about 5%). Preferably, the polypropylene fibers also have an elongation to break less than about 20%.

Additionally a novel class of fibers of the invention are polypropylene fibers possessing a modulus of at least about 220 g/denier, preferably at least about 250 g/denier.

The gel fibers containing first solvent, gel fibers containing second solvent and xerogel fibers of the present invention also represent novel articles of manufacture, distinguished from somewhat similar products described by Smook et al. and by Kalb and Pennings in having a volume porosities of 10% or less compared to values of 23%–65% in the references.

In particular the second gel fibers differ from the comparable prior art materials in having a solvent with an atmospheric boiling point less than about 50° C. As indicated by Examples 100–108, below, the uniformity and cylindrical shape of the xerogel fibers improved progressively as the boiling point of the second solvent declined. As also indicated in Examples 100–108 (see Table III), substantially higher tenacity fibers were produced under equivalent drying and stretching conditions by using trichlorotrifluoroethane (boiling point 47.5° C.) as the second solvent compared to fibers produced by using hexane (boiling point 68.7° C.) as second solvent. The improvement in final fiber is then directly attributable to changes in the second solvent in the second gel fiber. Preferred such second solvents are halogenated hydrocarbons of the proper boiling point such as methylene chloride (dichloromethane) and trichlorotrifluoroethane, with the latter being most preferred.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 5 illustrates in schematic form a first process to produce the novel fibers, wherein the stretching step F is conducted in two stages on the novel xerogel fiber subsequent to drying step E. In FIG. 5, a first mixing vessel 10 is shown, which is fed with an ultra high molecular weight polymer 11 such as polyethylene of weight average molecular weight at least 500,000 and preferably at least 1,000,000, and to which is also fed a first, relatively non-volatile solvent 12 such as paraffin oil. First mixing vessel 10 is equipped with an agitator 13. The residence time of polymer and first solvent in first mixing vessel 10 is sufficient to form a slurry containing some dissolved polymer and some relatively finely divided polymer particles, which slurry is removed in line 14 to an intensive mixing vessel 15. Intensive mixing vessel 15 is equipped with helical agitator blades 16. The residence time and agitator speed in intensive mixing vessel 15 is sufficient to convert the slurry into a solution. It will be appreciated that the

8

temperature in intensive mixing vessel 15, either because of external heating, heating of the slurry 14, heat generated by the intensive mixing, or a combination of the above is sufficiently high (e.g. 200° C.) to permit the polymer to be completely dissolved in the solvent at the desired concentration (generally between about 6 and about 10 percent polymer, by weight of solution). From the intensive mixing vessel 15, the solution is fed to an extrusion device 18, containing a barrel 19 within which is a screw 20 operated by motor 22 to deliver polymer solution at reasonably high pressure to a gear pump and housing 23 at a controlled flow rate. A motor 24 is provided to drive gear pump 23 and extrude the polymer solution, still hot, through a spinnerette 25 comprising a plurality of apertures, which may be circular, X-shaped, or, oval-shaped, or in any of a variety of shapes having a relatively small major axis in the plane of the spinnerette when it is desired to form fibers, and having a rectangular or other shape with an extended major axis in the plane of the spinnerette when it is desired to form films. The temperature of the solution in the mixing vessel 15, in the extrusion device 18 and at the spinnerette 25 should all equal or exceed a first temperature (e.g. 200° C.) chosen to exceed the gelation temperature (approximately 100–130 C. for polyethylene in paraffin oil). The temperature may vary (e.g. 220° C., 210° C. and 200° C.) or may be constant (e.g. 220° C.) from the mixing vessel 15 to extrusion device 18 to the spinnerette 25. At all points, however, the concentration of polymer in the solution should be substantially the same. The number of apertures, and thus the number of fibers formed, is not critical, with convenient number of apertures being 16, 120, or 240.

From the spinnerette 25, the polymer solution passes through an air gap 27, optionally enclosed and filled with an inert gas such as nitrogen, and optionally provided with a flow of gas to facilitate cooling. A plurality of gel fibers 28 containing first solvent pass through the air gap 27 and into a quench bath 30, so as to cool the fibers, both in the air gap 27 and in the quench bath 30, to a second temperature at which the solubility of the polymer in the first solvent is relatively low, such that most of the polymer precipitates as a gel material. While some stretching in the air gap 27 is permissible, it is preferably less than about 2:1, and is more preferably much lower. Substantial stretching of the hot gel fibers in air gap 27 is believed highly detrimental to the properties of the ultimate fibers.

It is preferred that the quench liquid in quench bath 30 be water. While the second solvent may be used as the quench fluid (and quench bath 30 may even be integral with solvent extraction device 37 described below), it has been found in limited testing that such a modification impairs fiber properties.

Rollers 31 and 32 in the quench bath 30 operate to feed the fiber through the quench bath, and preferably operate with little or no stretch. In the event that some stretching does occur across rollers 31 and 32, some first solvent exudes out of the fibers and can be collected as a layer in quench bath 30.

From the quench bath 30, the cool first gel fibers 33 pass to a solvent extraction device 37 where a second solvent, being of relatively low boiling such as trichlorotrifluoroethane, is fed in through line 38. The solvent outflow in line 40 contains second solvent and essentially all of the first solvent brought it with the cool gel fibers 33, either dissolved or dispersed in the second solvent. Thus the second gel fibers 41 conducted

4,413,110

9

out of the solvent extraction device 37 contain substantially only second solvent, and relatively little first solvent. The second gel fibers 41 may have shrunken somewhat compared to the first gel fibers 33, but otherwise contain substantially the same polymer morphology.

In a drying device 45, the second solvent is evaporated from the second gel fibers 41 forming essentially unstretched xerogel fibers 47 which are taken up on spool 52.

From spool 52, or from a plurality of such spools if it is desired to operate the stretching line at a slower feed rate than the take up of spool 52 permits, the fibers are fed over driven feed roll 54 and idler roll 55 into a first heated tube 56, which may be rectangular, cylindrical or other convenient shape. Sufficient heat is applied to the tube 56 to cause the internal temperature to be between about 120 and 140° C. The fibers are stretched at a relatively high draw ratio (e.g. 10:1) so as to form partially stretched fibers 58 taken up by driven roll 61 and idler roll 62. From rolls 61 and 62, the fibers are taken through a second heated tube 63, heated so as to be at somewhat higher temperature, e.g. 130-160° C. and are then taken up by driven take-up roll 65 and idler roll 66, operating at a speed sufficient to impart a stretch ratio in heated tube 63 as desired, e.g. about 2.5:1. The twice stretched fibers 68 produced in this first embodiment are taken up on take-up spool 72.

With reference to the six process steps of the process, it can be seen that the solution forming step A is conducted in mixers 13 and 15. The extruding step B is conducted with device 18 and 23, and especially through spinnerette 25. The cooling step C is conducted in airgap 27 and quench bath 30. Extraction step D is conducted in solvent extraction device 37. The drying step E is conducted in drying device 45. The stretching step F is conducted in elements 52-72, and especially in heated tubes 56 and 63. It will be appreciated, however, that various other parts of the system may also perform some stretching, even at temperatures substantially below those of heated tubes 56 and 63. Thus, for example, some stretching (e.g. 2:1) may occur within quench bath 30, within solvent extraction device 37, within drying device 45 or between solvent extraction device 37 and drying device 45.

A second process to produce the novel fiber products is illustrated in schematic form by FIG. 6. The solution forming and extruding steps A and B of the second embodiment are substantially the same as those in the first embodiment illustrated in FIG. 5. Thus, polymer and first solvent are mixed in first mixing vessel 10 and conducted as a slurry in line 14 to intensive mixing device 15 operative to form a hot solution of polymer in first solvent. Extrusion device 18 impels the solution under pressure through the gear pump and housing 23 and then through a plurality of apertures in spinnerette 27. The hot first gel fibers 28 pass through air gap 27 and quench bath 30 so as to form cool first gel fibers 33.

The cool first gel fibers 33 are conducted over driven roll 54 and idler roll 55 through a heated tube 57 which, in general, is longer than the first heated tube 56 illustrated in FIG. 5. The length of heated tube 57 compensates, in general, for the higher velocity of fibers 33 in the second embodiment of FIG. 6 compared to the velocity of xerogel fibers (47) between take-up spool 52 and heated tube 56 in the first embodiment of FIG. 5. The fibers 33 are drawn through heated tube 57 by

10

driven take-up roll 59 and idler roll 60, so as to cause a relatively high stretch ratio (e.g. 10:1). The once-stretched, first gel fibers 35 are conducted into extraction device 37.

In the extraction device 37, the first solvent is extracted out of the gel fibers by second solvent and the novel gel fibers 42 containing second solvent are conducted to a drying device 45. There the second solvent is evaporated from the gel fibers; and novel xerogel fibers 48, being once-stretched, are taken up on spool 52.

Fibers on spool 52 are then taken up by driven feed roll 61 and idler 62 and passed through a heated tube 63, operating at the relatively high temperature of between about 130° and 160° C. The fibers are taken up by driven take up roll 65 and idler roll 66 operating at a speed sufficient to impart a stretch in heated tube 63 as desired, e.g. about 2.5:1. The twice-stretched fibers 69 produced in the second embodiment are then taken up on spool 72.

It will be appreciated that, by comparing the embodiment of FIG. 6 with the embodiment of FIG. 5, the stretching step F has been divided into two parts, with the first part conducted in heated tube 57 performed on the first gel fibers 33 prior to extraction (D) and drying (E), and the second part conducted in heated tube 63, being conducted on xerogel fibers 48 subsequent to drying (E).

A third process to produce novel fiber products is illustrated in FIG. 7, with the solution forming step A, extrusion step B; and cooling step C being substantially identical to the first embodiment of FIG. 5 and the second embodiment of FIG. 6. Thus, polymer and first solvent are mixed in first mixing vessel 10 and conducted as a slurry in line 14 to intensive mixing device 15 operative to form a hot solution of polymer in first solvent. Extrusion device 18 impels the solution under pressure through the gear pump and housing 23 and then through a plurality of apertures in spinnerette 27. The hot first gel fibers 28 pass through air gap 27 and quench bath 30 so as to form cool first gel fibers 33.

The cool first gel fibers 33 are conducted over driven roll 54 and idler roll 55 through a heated tube 57 which, in general, is longer than the first heated tube 56 illustrated in FIG. 5. The length of heated tube 57 compensates, in general, for the higher velocity of fibers 33 in the third embodiment of FIG. 7 compared to the velocity of xerogel fibers (47) between take-up spool 52 and heated tube 56 in the first embodiment of FIG. 5. The first gel fibers 33 are now taken up by driven roll 61 and idler roll 62, operative to cause the stretch ratio in heated tube 57 to be as desired, e.g. 10:1.

From rolls 61 and 62, the once-drawn first gel fibers 35 are conducted into modified heated tube 64 and drawn by driven take up roll 65 and idler roll 66. Driven roll 65 is operated sufficiently fast to draw the fibers in heated tube 64 at the desired stretch ratio, e.g. 2.5:1. Because of the relatively high line speed in heated tube 64, required generally to match the speed of once-drawn gel fibers 35 coming off of rolls 61 and 62, heated tube 64 in the third embodiment of FIG. 7 will, in general, be longer than heated tube 63 in either the second embodiment of FIG. 6 or the first embodiment of FIG. 5. While first solvent may exude from the fiber during stretching in heated tubes 57 and 64 (and be collected at the exit of each tube), the first solvent is sufficiently non-volatile so as not to evaporate to an appreciable extent in either of these heated tubes.

4,413,110

11

The twice-stretched first gel fiber 36 is then conducted through solvent extraction device 37, where the second, volatile solvent extracts the first solvent out of the fibers. The second gel fibers, containing substantially only second solvent, is then dried in drying device 45, and the twice-stretched fibers 70 are then taken up on spool 72.

It will be appreciated that, by comparing the third embodiment of FIG. 7 to the first two embodiments of FIGS. 5 and 6, the stretching step (F) is performed in the third embodiment in two stages, both subsequent to cooling step C and prior to solvent extracting step D.

The invention will be further illustrated by the examples below. The first example illustrates the prior art techniques of Smook et. al. and the Kalb and Pennings articles.

COMPARATIVE EXAMPLE 1

A glass vessel equipped with a PTFE paddle stirrer was charged with 5.0 wt% linear polyethylene (sold as Hercules UHMW 1900, having 24 IV and approximately 4×10^6 M.W.), 94.5 wt% paraffin oil (J. T. Baker, 345-355 Saybolt viscosity) and 0.5 wt% antioxidant (sold under the trademark Ionol).

The vessel was sealed under nitrogen pressure and heated with stirring to 150° C. The vessel and its contents were maintained under slow agitation for 48 hours. At the end of this period the solution was cooled to room temperature. The cooled solution separated into two phases-A "mushy" liquid phase consisting of 0.43 wt% polyethylene and a rubbery gel phase consisting of 8.7 wt% polyethylene. The gel phase was collected, cut into pieces and fed into a 2.5 cm (one inch) Sterling extruder equipped with a $\frac{21}{1}$ L/D polyethylene-type screw. The extruder was operated at 10 RPM, 170° C. and was equipped with a conical single hole spinning die of 1 cm inlet diameter, 1 mm exit diameter and 6 cm length.

The deformation and compression of the gel by the extruder screw caused exudation of paraffin oil from the gel. This liquid backed up in the extruder barrel and was mostly discharged from the hopper end of the extruder. At the exit end of the extruder a gel fiber of approximately 0.7 mm diameter was collected at the rate of 1.6 m/min. The gel fiber consisted of 24-38 wt% polyethylene. The solids content of the gel fiber varied substantially with time.

The paraffin oil was extracted from the extruded gel fiber using hexane and the fiber was dried under vacuum at 50° C. The dried gel fiber had a density of 0.326 g/cm³. Therefore, based on a density of 0.960 for the polyethylene constituent, the gel fiber consisted of 73.2 volume percent voids. Measurement of pore volume using a mercury porosimeter showed a pore volume of 2.58 cm³/g. A B.E.T. measurement of surface area gave a value of 28.8 m²/g.

The dried fiber was stretched in a nitrogen atmosphere within a hot tube of 1.5 meters length. Fiber feed speed was 2 cm/min. Tube temperature was 100° C. at the inlet increasing to 150° C. at the outlet.

It was found that, because of filament nonuniformity, stretch ratios exceeding 30/1 were not sustainable for periods exceeding about 20 minutes without filament breakage.

The properties of the fiber prepared at 30/1 stretch ratio were as follows:

denier—99
tenacity—23 g/d

12

modulus—980 g/d

elongation at break—3%

work-to-break—6570 in lbs./in³ (45 MJ/m³)

The following example is illustrative of the present invention:

EXAMPLE 2

An oil jacketed double helical (Helicone®) mixer constructed by Atlantic Research Corporation was charged with 5.0 wt% linear polyethylene (Hercules UHMW 1900 having a 17 IV and approximately 2.5×10^6 M.W.) and 94.5 wt% paraffin oil (J. T. Baker, 345-355 Saybolt viscosity). The charge was heated with agitation at 20 rpm to 200° C. under nitrogen pressure over a period of two hours. After reaching 200° C., agitation was maintained for an additional two hours.

The bottom discharge opening of the Helicone mixer was fitted with a single hole capillary spinning die of 2 mm diameter and 9.5 mm length. The temperature of the spinning die was maintained at 200° C.

Nitrogen pressure applied to the mixer and rotation of the blades of the mixer were used to extrude the charge through the spinning die. The extruded uniform solution filament was quenched to a gel state by passage through a water bath located at a distance of 33 cm (13 inches) below the spinning die. The gel filament was wound up continuously on a 15.2 cm (6 inch) diameter bobbin at the rate of 4.5 meters/min.

The bobbins of gel fiber were immersed in trichlorotrifluoroethane (fluorocarbon 113 or "TCTFE") to exchange this solvent for paraffin oil as the liquid constituent of the gel. The gel fiber was unwound from a bobbin, and the fluorocarbon solvent evaporated at 22°-50° C.

The dried fiber was of 970±100 denier. The density of the fiber was determined to be 950 kg/m³ by the density gradient method. Therefore, based on a density of 960 kg/m³ for the polyethylene constituent, the dried fiber contained one volume percent voids. A B.E.T. measurement of the surface area gave a value less than 1 m²/g.

The dried gel fiber was fed at 2 cm/min into a hot tube blanketed with nitrogen and maintained at 100° C. at its inlet and 140° C. at its outlet. The fiber was stretched continuously 45/1 within the hot tube for a period of three hours without experiencing fiber breakage. The properties of the stretched fiber were:

denier—22.5
tenacity—37.6 g/d
modulus—1460 g/d
elongation—4.1%
work-to-break—12,900 in-lbs/in³ (89 MJ/m³)

EXAMPLES 3-99

A series of fiber samples was prepared following the procedures described in Example 2, but with variations introduced in the following material and process parameters:

- polyethylene IV (molecular weight)
- polymer gel concentration
- stretch temperature
- fiber denier
- stretch ratio

The results of these experiments upon the final fiber properties obtained are presented in Table I. The Polymer intrinsic viscosity values were 24 in Examples 3-49 and 17 in Examples 50-99. The gel concentration was

13

2% in Examples 26-41, 4% in Examples 3-17, 5% in Examples 42-99 and 6% in Examples 18-25.

TABLE I

Ex.	Stretch Temp., °C	Stretch Ratio	Denier	Tenacity g/d	Modulus g/d	Elong %
3	142	15.6	2.8	17.8	455.	6.7
4	145	15.5	2.8	18.6	480.	6.7
5	145	19.6	2.2	19.8	610.	5.2
6	145	13.0	3.4	13.7	350.	6.2
7	145	16.6	2.7	15.2	430.	5.7
8	144	23.9	1.8	23.2	730.	4.9
9	150	16.0	2.7	14.6	420.	5.0
10	150	27.3	1.6	21.6	840.	4.0
11	149	23.8	1.8	21.8	680.	4.6
12	150	27.8	1.6	22.6	730.	4.3
13	140	14.2	3.1	16.5	440.	5.3
14	140	22.0	2.0	21.7	640.	4.7
15	140	25.7	1.7	26.1	810.	4.7
16	140	3.4	5.6	11.2	224.	18.0
17	140	14.9	2.9	20.8	600.	5.6
18	145	19.5	11.7	16.4	480.	6.3
19	145	11.7	19.4	16.3	430.	6.1
20	145	22.3	10.2	24.1	660.	5.7
21	145	47.4	4.8	35.2	1230.	4.3
22	150	15.1	15.0	14.0	397.	6.5
23	150	56.4	4.0	28.2	830.	4.4
24	150	52.8	4.3	36.3	1090.	4.5
25	150	12.8	17.8	19.1	440.	7.2
26	143	10.3	21.4	8.7	178.	7.0
27	146	1.8	120.0	2.1	22.	59.7
28	146	3.2	69.5	2.7	37.	40.5
29	145	28.0	7.9	16.0	542.	4.9
30	145	50.2	4.4	21.6	725.	4.0
31	145	30.7	7.2	22.7	812.	4.2
32	145	10.2	21.8	16.2	577.	5.6
33	145	22.3	9.9	15.3	763.	2.8
34	150	28.7	7.7	10.5	230.	8.4
35	150	12.1	18.3	12.6	332.	5.2
36	150	8.7	25.5	10.9	308.	5.9
37	150	17.4	12.7	14.1	471.	4.6
38	140	12.0	18.5	12.7	357.	7.3
39	140	21.5	10.3	16.1	619.	4.2
40	140	36.8	6.0	23.8	875.	4.1
41	140	59.7	3.7	26.2	1031.	3.6
42	145	13.4	25.0	12.9	344.	8.3
43	145	24.4	13.7	22.3	669.	5.9
44	145	25.2	13.3	23.2	792.	4.9
45	145	33.5	10.0	29.5	1005.	4.9
46	150	17.2	19.5	14.2	396.	5.6
47	150	16.0	21.0	15.7	417.	7.2
48	140	11.2	30.0	13.1	316.	8.3
49	140	21.0	16.0	23.0	608.	6.0
50	130	15.8	64.9	14.2	366.	6.0
51	130	44.5	23.1	30.8	1122.	4.4
52	130	24.3	42.4	26.8	880.	4.7
53	130	26.5	38.8	23.6	811.	4.2
54	140	11.0	93.3	14.5	303.	8.4
55	140	28.3	36.3	24.7	695.	4.8
56	140	43.4	23.7	30.3	905.	4.8
57	140	18.4	55.9	19.7	422.	6.6
58	150	15.7	65.5	12.8	337.	8.6
59	150	43.4	23.7	30.9	1210.	4.5
60	150	33.6	30.6	28.9	913.	4.8
61	150	54.4	18.9	30.2	1134.	3.7
62	150	13.6	71.1	10.4	272.	12.2
63	150	62.9	15.4	30.5	1008.	4.0
64	150	26.6	36.4	20.4	638.	7.0
65	150	36.1	26.8	32.0	1081.	5.3
66	150	52.0	18.6	34.0	1172.	4.1
67	150	73.3	13.2	35.3	1314.	3.8
68	140	14.6	66.1	13.9	257.	14.9
69	140	30.1	32.1	28.5	933.	4.5
70	140	45.6	21.2	35.9	1440.	3.9
71	140	43.0	22.5	37.6	1460.	4.1
72	140	32.3	30.1	33.1	1170.	4.3
73	140	57.3	16.9	39.6	1547.	3.8
74	130	16.3	59.4	21.6	556.	5.5
75	130	20.6	47.0	25.6	752.	5.3
76	130	36.3	26.7	33.0	1144.	4.1
77	130	49.4	19.6	30.4	1284.	3.8
78	130	24.5	44.6	26.4	990.	4.5

4,413,110.

14

TABLE I-continued

Ex.	Stretch Temp., °C	Stretch Ratio	Denier	Tenacity g/d	Modulus g/d	Elong %
5	79	130	28.6	38.2	27.1	975.
	80	130	42.2	25.9	34.7	1200.
	81	140	40.3	27.1	33.2	1260.
	82	140	58.7	18.6	35.5	1400.
	83	145	47.9	22.8	32.1	1460.
10	84	145	52.3	20.9	37.0	1500.
	85	130	13.6	80.4	12.8	275.
	86	130	30.0	36.4	24.8	768.
	87	130	29.7	36.8	28.6	1005.
	88	140	52.0	21.0	36.0	1436.
	89	140	11.8	92.3	10.1	151.
15	90	140	35.3	31.0	29.8	1004.
	91	140	23.4	46.8	26.6	730.
	92	150	14.6	74.9	11.5	236.
	93	150	35.7	30.6	27.4	876.
	94	150	31.4	34.8	27.0	815.
	95	150	37.8	28.9	29.8	950.
20	96	150	15.9	68.7	9.8	210.
	97	150	30.2	36.2	24.6	799.
	98	150	36.1	30.3	28.2	959.
	99	150	64.7	16.9	32.1	1453.

In order to determine the relationships of the fiber properties to the process and material parameters, the data of Table I were subjected to statistical analysis by multiple linear regression. The regression equation obtained for fiber tenacity was as follows:

$$\text{Tenacity, g/d} = -8.47 + 2.00 \cdot \text{SR} + 0.491 \cdot \text{IV} + 0.0605 \cdot \text{C} \cdot \text{SR} - 0.00623 \cdot \text{T} \cdot \text{SR} - 0.0156 \cdot \text{IV} \cdot \text{SR} - 0.00919 \cdot \text{SR} \cdot \text{SR}$$

Where

SR is stretch ratio
IV is polymer intrinsic viscosity in decalin at 135° C., dl/g
C is polymer concentration in the gel, wt%
T is stretch temp. °C.

The statistics of the regression were:

F ratio (6,95)=118

significance level=99.9+%

standard error of estimate=3.0 g/d

A comparison between the observed tenacities and tenacities calculated from the regression equation is shown in FIG. 1.

FIGS. 2 and 3 present response surface contours for tenacity calculated from the regression equation on two important planes.

In the experiments of Examples 3-99, a correlation of modulus with spinning parameters was generally parallel to that of tenacity. A plot of fiber modulus versus tenacity is shown in FIG. 4.

It will be seen from the data, the regression equations and the plots of the calculated and observed results that the method of the invention enables substantial control to obtain desired fiber properties and that greater controllability and flexibility is obtained than by prior art methods.

Further, it should be noted that many of the fibers of these examples showed higher tenacities and/or modulus values than had been obtained by prior art methods. In the prior art methods of Off. 30 04 699 and GB 2051667, all fibers prepared had tenacities less than 3.0 GPa (35 g/d) and moduli less than 100 GPa (1181 g/d). In the present instance, fiber examples Nos. 21, 67, 70, 73, 82, 84 and 88 exceeded both of these levels and other fiber examples surpassed on one or the other property.

15

4,413,110

In the prior art publications of Pennings and coworkers, all fibers (prepared discontinuously) had moduli less than 121 GPa (1372 g/d). In the present instance continuous fiber examples No. 70, 71, 73, 82, 83, 84, 88 and 99 surpassed this level.

The fiber of example 71 was further tested for resistance to creep at 23° C. under a sustained load of 10% of the breaking load. Creep is defined as follows:

$$\% \text{ Creep} = 100 \times (A(s,t) - B(s)) / B(s)$$

where:

B(s) is the length of the test section immediately after application of load

A(s,t) is the length of the test section at time t after application of load, s

A and B are both functions of the loads, while A is also a function of time t.

For comparison, a commercial nylon tire cord (6 denier, 9.6 g/d tenacity) and a polyethylene fiber prepared in accordance with Ser. No. 225,288, filed Jan. 15, 1981 by surface growth and subsequent hot stretching (10 denier, 41.5 g/d tenacity) were similarly tested for creep.

The results of these tests are presented in Table II.

TABLE II

CREEP RESISTANCE AT 23° C.
Load: 10% of Breaking Load

Time After Application of Load, Days	% Creep		
	Fiber of Example 71	Comparative Nylon Tire Cord	Surface Grown & Stretched Polyethylene
1	0.1	4.4	1.0
2	0.1	4.6	1.2
6	—	4.8	1.7
7	0.4	—	—
9	0.4	—	—
12	—	4.8	2.1
15	0.6	4.8	2.5
19	—	4.8	2.9
21	0.8	—	—
22	—	4.8	3.1
25	0.8	—	—
26	—	4.8	3.6
28	0.9	—	—
32	0.9	—	—
33	—	4.8	4.0
35	1.0	—	—
39	1.4	—	—
40	—	4.9	4.7
43	1.4	—	—
47	1.4	—	—
50	—	4.9	5.5
51	1.4	—	—
57	—	4.9	6.1
59	1.45	—	—

It will be seen that the fiber of example 71 showed about 1.4% creep in 50 days at 23° C. under the sustained load equal to 10% of the breaking load. By way of comparison, both the commercial nylon 6 tire cord and the surface grown polyethylene fiber showed about 5% creep under similar test conditions.

The melting temperatures and the porosities of the fibers of examples 64, 70 and 71 were determined. Melting temperatures were measured using a DuPont 990 differential scanning calorimeter. Samples were heated in an argon atmosphere at the rate of 10° C./min. Additionally, the melting temperature was determined for the starting polyethylene powder from which the fibers of examples 64, 70 and 71 were prepared.

Porosities of the fibers were determined by measurements of their densities using the density gradient tech-

16

nique and comparison with the density of a compression molded plaque prepared from the same initial polyethylene powder. (The density of the compression molded plaque was 960 kg/m³).

Porosity was calculated as follows:

$$\% \text{ Porosity} = \frac{960 - \text{fiber density, kg/m}^3}{960}$$

Results were as follows:

Sample	Melting Temp. °C.	Fiber Density, Kg/m ³	Porosity, %
15 Polyethylene powder	138	—	—
Fiber of Example 64	149	982	0
Fiber of Example 70	149	976	0
Fiber of Example 71	150	951	1

The particular level and combination of properties exhibited by the fiber of examples 64, 70 and 71, i.e., tenacity at least about 30 g/d, modulus in excess of 1000 g/d, and creep (at 23° C. and 10% of breaking load) less than 3% in 50 days, melting temperature of at least about 147° C. and porosity less than about 10% appears not to have been attained heretofore.

The following examples illustrate the effect of the second solvent upon fiber properties.

EXAMPLES 100-108

Fiber samples were prepared as described in Example 2, but with the following variations. The bottom discharge opening of the Helicone mixer was adapted to feed the polymer solution first to a gear pump and thence to a single hole conical spinning die. The cross-section of the spinning die tapered uniformly at a 7.5° angle from an entrance diameter of 10 mm to an exit diameter of 1 mm. The gear pump speed was set to deliver 5.84 cm³/min of polymer solution to the die. The extruded solution filament was quenched to a gel state by passage through a water bath located at a distance of 20 cm below the spinning die. The gel filament was wound up continuously on bobbins at the rate of 7.3 meters/min.

The bobbins of gel fiber were immersed in several different solvents at room temperature to exchange with the paraffin oil as the liquid constituent of the gel. The solvents and their boiling points were:

Solvent	Boiling Point, °C.
diethyl ether	34.5
n-pentane	36.1
methylene chloride	39.8
trichlorotrifluoroethane	47.5
n-hexane	68.7
carbon tetrachloride	76.8
n-heptane	98.4
dioxane	101.4
toluene	110.6

The solvent exchanged gel fibers were air dried at room temperature. Drying of the gel fibers was accompanied in each case by substantial shrinkage of transverse dimensions. Surprisingly, it was observed that the shape and surface texture of the xerogel fibers departed progressively from a smooth cylindrical form in approximate proportion to the boiling point of the second solvent. Thus, the fiber from which diethyl ether had

17

been dried was substantially cylindrical whereas the fiber from which toluene had been dried was "C" shaped in cross-section.

The xerogel fibers prepared using TCTFE and n-hexane as second solvents were further compared by stretching each at 130° C., incrementally increasing stretch ratio until fiber breakage occurred. The tensile properties of the resulting fibers were determined as shown in Table III.

It will be seen that the xerogel fiber prepared using TCTFE as the second solvent could be stretched continuously to a stretch ratio of 49/1 and whereas the xerogel fiber prepared using n-hexane could be stretched continuously only to a stretch ratio of 33/1. At maximum stretch ratio, the stretched fiber prepared using TCTFE second solvent was of 39.8 g/d tenacity, 1580 g/d modulus. This compares to 32.0 g/d tenacity, 1140 g/d modulus obtained using n-hexane as the second solvent.

TABLE III

Properties of Xerogel Fibers Stretched at 130° C. Feed Speed: 2.0 cm/min.					
Example	Second Solvent	Stretch Ratio	Tenacity g/d	Modulus g/d	Elong. %
100	TCTFE	16.0	23.3	740	5.0
101	TCTFE	21.8	29.4	850	4.5
102	TCTFE	32.1	35.9	1240	4.5
103	TCTFE	40.2	37.4	1540	3.9
104	TCTFE	49.3	39.8	1580	4.0
105	n-hexane	24.3	28.4	1080	4.8
106	n-hexane	26.5	29.9	920	5.0
107	n-hexane	32.0	31.9	1130	4.5
108	n-hexane	33.7	32.0	1140	4.5

EXAMPLE 110

Following the procedures of Examples 3-99, an 8 wt% solution of isotactic polypropylene of 12.8 intrinsic viscosity (in decalin at 135° C.), approximately 2.1×10^6 M.W. was prepared in paraffin oil at 200° C. A gel fiber was spun at 6.1 meters/min. The paraffin oil was solvent exchanged with TCTFE and the gel fiber dried at room temperature. The dried fiber was stretched 25/1 at a feed roll speed of 2 cm/min. Stretching was conducted in a continuous manner for one hour at 160° C.

Fiber properties were as follows:

denier—105
tenacity—9.6 g/d
modulus—164 g/d
elongation—11.5%
work-to-break—9280 in lbs/in² (64 MJ/m²)

EXAMPLES 111-486

A series of xerogel fiber samples was prepared as in Example 2 but using a gear pump to control melt flow rate. Variations were introduced in the following material and process parameters:

- polyethylene IV (molecular weight)
- polymer gel concentration
- die exit diameter
- die included angle (conical orifice)
- spinning temperature
- melt flow rate
- distance to quench
- gel fiber take-up velocity
- xerogel fiber denier

Each of the xerogel fiber samples prepared was stretched in a hot tube of 1.5 meter length blanketed

4,413,110

18

with nitrogen and maintained at 100° C. at the fiber inlet and 140° C. at the fiber outlet. Fiber feed speed into the hot tube was 4 cm/min. (Under these conditions the actual fiber temperature was within 1° C. of the tube temperature at distances beyond 15 cm from the inlet). Each sample was stretched continuously at a series of increasing stretch ratios. The independent variables for these experiments are summarized below:

Polymer Intrinsic Viscosity (dL/g)

- 11.5—Examples 172-189, 237-241, 251-300, 339-371
15.5—Examples 111-126, 138-140, 167-171, 204-236, 242-243, 372-449, 457-459
17.7—Examples 127-137, 141-166, 190-203, 244-250, 301-338
20.9—Examples 450-456, 467-486

Gel Concentration

- 5% Examples 127-137, 141-149, 167-171, 190-203, 244-260, 274-276, 291-306, 339-371
6% Examples 111-126, 138-140, 204-236, 242-243, 372-418, 431-486
7% Examples 150-166, 172-189, 237-241, 261-273, 277-290, 307-338

Die Diameter

Inches	Millimeters	
0.04	1	Examples 167-171, 237-241, 244-260, 274-276, 282-290, 301-306, 317-338, 366-371 and 460-466
0.08	2	Examples 111-166, 172-236, 242, 243, 261-273, 277-281, 291-300, 307-316, 339-365, 372-459 and 467-486.

Die Angle (Degrees)

- 0° Examples 127-137, 141-149, 261-281, 307-316, 339-365, 419-430
7.5° Examples 111-126, 138-140, 167-171, 204-243, 251-260, 301-306, 317-338, 372-418, 431-486
15° Examples 150-166, 172-203, 244-250, 282-300, 366-371

Spinning Temperature

- 180° C. Examples 172-203, 237-241, 301-322, 339-371
200° C. Examples 111-126, 138-140, 167-171, 204-236, 242-243, 372-486
220° C. Examples 127-137, 141-166, 244-300, 323-338

Solution Flow Rate (cm³/min)

- 2.92 ± 0.02 Examples 116-122, 135-145, 150-152, 162-166, 172-173, 196-201, 214-222, 237, 240, 242-245, 251-255, 260-265, 277-284, 288-293, 301, 304-306, 310-312, 318-320, 347-360, 368-370, 372, 395-397, 401-407, 412-414, 419-424, 450-459, 467-481
4.37 ± 0.02 Examples 204-208, 230-236, 377-379, 408-411
5.85 ± 0.05 Examples 111-115, 123-134, 146-149, 153-161, 167-171, 180-195, 202-203, 209-213, 223-229, 238-239, 241, 256-259, 266-276, 285-287, 294-300, 302-303, 307-309, 315-317, 321-326, 335-338, 361-367, 371, 373-376, 392-394, 398-400, 415-418, 431-433, 482-486
6.07 Examples 339-346

4,413,110

19

-continued

8.76	Examples 380-391
8.88	Examples 246-250
11.71 ± 0.03	Examples 434-437, 445-449
17.29	Examples 438-440
Distance to Quench	
Inches	Millimeters
5.5	140
6.0	152
6.5	165
7.7	196
13.0	330
14.5	368
15.0	381
22.5	572
23.6	600
24.0	610

Under all of the varied conditions, the take-up velocity varied from 90-1621 cm/min, the xerogel fiber denier from 98-1613, the stretch ratio from 5-174, the tenacity from 9-45 g/denier, the tensile modulus from 218-1700 g/denier and the elongation from 2.5-29.4%.

The results of each Example producing a fiber of at least 30 g/denier (2.5 GPa) tenacity or at least 1000 g/denier (85 GPa) modulus are displayed in Table IV.

TABLE IV

Stretched Fiber Properties					
Example	Xerogel Fiber Denier	Stretch Ratio	Tenacity g/den	Modulus g/den	% Elong
113	1599.	50.	31.	1092.	4.0
114	1599.	57.	34.	1356.	3.6
115	1599.	72.	37.	1490.	3.5
119	1837.	63.	35.	1257.	4.2
122	1289.	37.	32.	988.	4.5
126	440.	41.	31.	1051.	4.5
128	1260.	28.	31.	816.	5.5
130	1260.	33.	33.	981.	4.5
131	1260.	43.	35.	1179.	4.0
132	1260.	40.	37.	1261.	4.5
133	1260.	39.	30.	983.	4.0
134	1260.	53.	36.	1313.	4.0
135	282.	26.	29.	1062.	3.5
136	282.	26.	30.	1034.	3.5
137	282.	37.	30.	1261.	3.5
140	168.	23.	26.	1041.	3.5
145	568.	40.	30.	1157.	4.0
146	231.	21.	32.	763.	4.0
147	231.	23.	36.	1175.	4.2
148	231.	22.	33.	1131.	4.0
149	231.	19.	31.	1090.	4.0
151	273.	31.	28.	1117.	3.5
157	1444.	64.	29.	1182.	3.0
160	408.	35.	30.	1124.	4.0
164	1385.	36.	32.	1210.	4.0
166	1385.	39.	33.	1168.	4.0
168	344.	26.	30.	721.	5.0
169	344.	40.	32.	1188.	4.0
170	344.	26.	30.	1060.	4.0
171	344.	29.	31.	1172.	4.0
179	1017.	68.	29.	1179.	4.0
182	352.	65.	33.	1146.	3.7
189	1958.	44.	27.	1050.	3.5
195	885.	59.	31.	1150.	4.0
201	496.	33.	29.	1082.	4.0
206	846.	37.	31.	955.	4.5
208	846.	63.	35.	1259.	3.5

20

TABLE IV-continued

Stretched Fiber Properties					
Example	Xerogel Fiber Denier	Stretch Ratio	Tenacity g/den	Modulus g/den	% Elong
212	368.	55.	39.	1428.	4.5
213	368.	49.	35.	1311.	4.0
220	1200.	81.	34.	1069.	4.0
221	1200.	60.	30.	1001.	4.0
227	1607.	42.	30.	1050.	4.0
228	1607.	47.	30.	1114.	3.5
229	1607.	53.	35.	1216.	4.0
233	1060.	34.	30.	914.	4.5
235	1060.	50.	37.	1279.	4.1
236	1060.	74.	45.	1541.	4.0
245	183.	23.	26.	1014.	4.0
247	247.	16.	30.	1005.	4.5
248	247.	10.	30.	1100.	4.0
249	247.	11.	31.	1132.	4.0
250	247.	19.	37.	1465.	3.8
251	165.	34.	31.	1032.	4.5
252	165.	33.	31.	998.	4.5
254	165.	41.	31.	1116.	4.0
255	165.	40.	29.	1115.	4.0
272	1200.	41.	24.	1122.	3.0
273	1200.	64.	27.	1261.	2.5
274	154.	27.	30.	854.	4.5
275	154.	44.	32.	1063.	4.5
276	154.	38.	30.	1054.	4.0
280	291.	39.	30.	978.	4.0
281	291.	43.	29.	1072.	4.0
284	254.	30.	32.	1099.	4.5
308	985.	27.	30.	900.	4.3
309	985.	34.	35.	1210.	3.8
311	306.	30.	31.	990.	4.4
312	306.	30.	32.	1045.	4.0
314	1234.	45.	37.	1320.	4.0
315	344.	25.	30.	970.	4.0
317	254.	29.	32.	1270.	3.5
320	190.	29.	30.	1060.	4.0
322	307.	25.	29.	1030.	4.0
323	340.	25.	34.	1293.	4.1
324	340.	23.	33.	996.	4.4
325	340.	30.	37.	1241.	4.1
326	340.	35.	39.	1480.	3.7
327	373.	24.	30.	920.	4.5
328	373.	27.	34.	1080.	4.5
329	373.	30.	36.	1349.	4.0
330	373.	35.	37.	1377.	3.9
332	218.	34.	35.	1320.	3.9
333	218.	30.	37.	1364.	4.0
334	218.	30.	31.	1172.	3.9
335	326.	26.	37.	1260.	4.5
336	326.	30.	39.	1387.	4.2
337	326.	42.	42.	1454.	4.0
338	326.	42.	37.	1440.	3.9
339	349.	55.	29.	1330.	3.3
345	349.	31.	29.	1007.	4.5
346	349.	51.	34.	1165.	4.3
357	772.	45.	31.	990.	4.4
358	772.	51.	27.	1356.	3.0
359	772.	58.	32.	1240.	3.7
360	772.	59.	33.	1223.	3.8
364	293.	47.	38.	1407.	4.5
375	1613.	50.	30.	960.	4.1
379	791.	46.	32.	1110.	3.9
382	1056.	68.	34.	1280.	3.7
383	921.	51.	31.	1090.	4.0
386	1057.	89.	34.	1250.	3.8
387	984.	59.	33.	1010.	4.3
394	230.	29.	31.	982.	4.3
400	427.	32.	30.	970.	4.1
405	1585.	39.	33.	1124.	3.6
407	1585.	174.	32.	1040.	4.0
418	1370.	51.	33.	1160.	3.7
419	344.	23.	30.	1170.	3.8
421	1193.	30.	31.	880.	4.6
422	1193.	39.	35.	1220.	3.9
423	1193.	51.	34.	1310.	3.4
424	1193.	50.	36.	1390.	3.6
426	1315.	32.	30.	860.	4.4
427	1315.	42.	33.	1160.	3.9

21

4,413,110

TABLE IV—continued

Stretched Fiber Properties					
Example	Xerogel Fiber Denier	Stretch Ratio	Tenacity g/den	Modulus g/den	% Elong
428	1315.	46.	34.	1170.	3.8
429	395.	19.	35.	840.	4.5
430	395.	25.	31.	1100.	3.9
435	1455.	36.	31.	920.	4.3
436	1455.	43.	31.	1120.	3.6
437	1455.	51.	33.	1060.	3.3
440	1316.	37.	32.	1130.	4.0
441	453.	31.	32.	990.	4.7
442	453.	49.	39.	1320.	4.4
443	453.	34.	33.	1060.	4.4
444	453.	55.	36.	1410.	3.6
446	402.	28.	30.	1107.	4.0
447	402.	22.	30.	870.	5.0
448	402.	34.	36.	1175.	4.3
449	402.	38.	37.	1256.	4.3
451	461.	33.	33.	1070.	4.4
452	461.	38.	35.	1130.	4.1
453	461.	40.	35.	1220.	3.7
454	64.	14.	34.	1080.	4.7
455	64.	17.	35.	1263.	3.4
456	64.	26.	40.	1453.	3.8
460	268.	32.	35.	1220.	4.3
462	268.	29.	34.	1100.	4.2
463	268.	32.	34.	1110.	4.1
464	268.	43.	40.	1390.	3.9
465	420.	53.	41.	1550.	3.7
466	420.	27.	31.	1010.	4.0
467	371.	24.	31.	960.	4.4
468	371.	63.	45.	1560.	3.9
470	1254.	40.	35.	1100.	4.1
471	1254.	43.	37.	1190.	4.0
472	1254.	45.	38.	1320.	4.0
473	1254.	66.	39.	1600.	3.5
474	210.	44.	43.	1700.	3.5
475	210.	21.	34.	1170.	4.0
476	210.	27.	38.	1420.	3.6
479	1227.	50.	34.	1180.	4.1
480	1227.	48.	33.	1140.	4.1
481	1227.	44.	35.	1230.	4.1
483	1294.	29.	31.	1000.	4.3
484	1294.	42.	36.	1350.	3.7
485	340.	26.	32.	1160.	3.8
486	340.	18.	27.	1020.	4.1

In order to determine the relationships of the fiber properties to the process and material parameters, all of the data from Example 111-486, including those Examples listed in Table IV, were subjected to statistical analysis by multiple linear regression. The regression equation obtained for fiber tenacity was as follows:

$$\begin{aligned} \text{Tenacity, g/d} = & 11.88 + 2.221\text{IV}' + 1.147\text{C}' + 1.948\text{TM}' \\ & + 0.822\text{Q}' - 1.167\text{L}' - 2.438\text{DO}' + 0.532\text{SR} \\ & - 0.7261\text{V}'\text{DA}' + 1.3991\text{V}'\text{TM}' + 0.5341\text{V}'\text{L}' \\ & + 0.0461\text{V}'\text{SR} - 0.754\text{C}'\text{DA}' - 0.391\text{C}'\text{Q}' - 0.419\text{C}'\text{DO}' \\ & - 1.327\text{D}'\text{TM}' + 0.366\text{D}'\text{L}' - 0.577\text{D}'\text{A}'\text{TM}' \\ & - 0.790\text{D}'\text{A}'\text{Q}' - 0.034\text{D}'\text{A}'\text{SR} - 0.049\text{TM}'\text{SR} \\ & + 0.809\text{Q}'\text{L}' - 0.313\text{Q}'\text{DO}' - 0.334(\text{IV}')^2 \\ & + 0.115(\text{L}')^2 + 0.564(\text{DO}')^2 - 0.00237(\text{SR})^2 \end{aligned}$$

where:

$$\text{IV}' = (\text{polymer IV, dL/g} - 14.4)/3.1$$

$$\text{C}' = \text{Gel concentration, \%} - 6$$

$$\text{TM}' = (\text{spinning temp. } ^\circ\text{C.} - 200)/20$$

$$\text{Q}' = (\text{spin flow rate, cc/min} - 4.38)/1.46$$

$$\text{L}' = (\text{distance to quench, in} - 15)/9$$

$$\text{DO}' = 1.4427 \log (\text{xerogel fiber denier}/500)$$

$$\text{SR} = \text{stretch ratio (xerogel fiber denier/stretched fiber denier)}$$

$$\text{DA}' = (\text{die angle, } ^\circ - 7.5)/7.5$$

$$\text{D}' = (\text{die exit diameter, inches} - 0.06)/0.02$$

22

The statistics of the regression were;

$$F \text{ ratio } (26, 346) = 69$$

$$\text{Significance Level} = 99.9 + \%$$

$$\text{Standard error of estimate} = 2.6 \text{ g/denier}$$

In the vicinity of the center of the experimental space these effects may be summarized by considering the magnitude of change in the factor which is required to increase tenacity of 1 g/d. This is given below.

Factor Change Required to Increase Tenacity By 1 g/denier		
Factor		
IV	+1	dL/g
Conc.	+1	wt %
Spin Temp.	+10	°C.
Spin Rate	±(saddle)	cc/min
Die Diam.	-0.010	inches
Die Angle	-2	degrees
Dist. to Quench	-4	inches
Xerogel Fiber Denier	-25	
Stretch Ratio	+2/1	

High fiber tenacity was favored by increasing polymer IV, increasing gel concentration, increasing spinning temperature, decreasing die diameter, decreasing distance to quench, decreasing xerogel fiber diameter, increasing stretch ratio and 0° die angle (straight capillary).

It will be seen that the method of the invention enables substantial control to obtain desired fiber properties and that greater controlability and flexibility is obtained than by prior art methods.

In these experiments, the effects of process parameters upon fiber modulus generally paralleled the effects of these variables upon tenacity. Fiber modulus was correlated with tenacity as follows

$$\text{modulus, g/d} = 42(\text{tenacity, g/d}) - 258$$

Significance of the correlation between modulus and tenacity was 99.99 + %. Standard error of the estimate of modulus was 107 g/d.

It should be noted that many of the fibers of these examples show higher tenacities and/or higher modulus than had been obtained by prior art methods.

The densities and porosities of several of the xerogel and stretched fibers were determined.

Example	Xerogel fiber		Stretched fiber	
	Density kg/m ³	% Porosity	Density, kg/m ³	% Porosity
115	934	2.7	—	—
122	958	0.2	0.965	0
126	958	0.2	—	—
182	906	5.6	940	2.1

The porosities of these samples were substantially lower than in the prior art methods cited earlier.

EXAMPLES 487-583

In the following examples of multi-filament spinning and stretching, polymer solutions were prepared as in Example 2. The solutions were spun through a 16 hole spinning die using a gear pump to control solution flow rate. The temperatures of the spinning die were straight capillaries of length-to-diameter ratio of 25/1. Each capillary was preceded by a conical entry region of 60° included angle.

23

The multi-filament solution yarns were quenched to a gel state by passing through a water bath located at a short distance below the spinning die. The gel yarns were wound up on perforated dye tubes.

EXAMPLES 487-495

ONE STAGE "DRY STRETCHING" OF MULTI-FILAMENT YARN

The wound tubes of gel yarn were extracted with TCTFE in a large Soxhlet apparatus to exchange this solvent for paraffin oil as the liquid constituent of the gel. The gel fiber was unwound from the tubes and the TCTFE solvent was evaporated at room temperature.

The dried xerogel yarns were stretched by passing the yarn over a slow speed feed godet and idler roll through a hot tube blanketed with nitrogen, onto a second godet and idler roller driven at a higher speed. The stretched yarn was collected on a winder.

It was noted that some stretching of the yarn (approximately 2/1) occurred as it departed the feed godet and before it entered the hot tube. The overall stretch ratio, i.e., the ratio of the surface speeds of the godets, is given below.

In examples 487-495, the diameter of each hole of the 16 filament spinning die was 0.040 inch (one millimeter) the spinning temperature was 220° C., the stretch temperature (in the hot tube) was 140° C. and the feed roll speed during stretching was 4 cm/min. In examples 487-490 the polymer IV was 17.5 and the gel concentration was 7 weight %. In examples 491-495 the polymer IV was 22.6. The gel concentration was 9 weight % in example 491, 8 weight % in examples 492-493 and 6 weight % in examples 494 and 495. The distance from the die face to the quench bath was 3 inches (7.52 cm) in examples 487, 488, 494 and 495 and 6 inches (15.2 cm) in examples 490-493. The other spinning conditions and the properties of the final yarns were as follows:

Ex. No.	Spin Rate cc/min-fil	Yarn Properties					Ten g/d	Mod g/d	% Elong
		Gel Fiber Take-up Speed cc/min	SR	Denier					
487	1.67	1176	35	41	36	1570	3.3		
488	2.86	491	25	136	27	1098	3.7		
489	2.02	337	25	132	29	1062	3.6		
490	2.02	337	30	126	31	1275	3.5		
491	1.98	162	25	151	33	1604	3.0		
492	1.94	225	25	227	29	1231	3.3		
493	1.94	225	30	143	34	1406	3.3		
494	1.99	303	30	129	34	1319	3.4		
495	1.99	303	35	112	35	1499	3.2		

EXAMPLES 496-501

ONE STAGE "WET STRETCHING" OF MULTI-FILAMENT YARN

The wound gel yarns still containing the paraffin oil were stretched by passing the yarn over a slow speed feed godet and idler roll through a hot tube blanketed with nitrogen onto a second godet and idler roll driven at high speed. It was noted that some stretching of the yarn (approximately 2/1) occurred as it departed the feed godet and before it entered the hot tube. The overall stretch ratio, i.e., the ratio of the surface speeds of the godets is given below. The stretching caused essentially no evaporation of the paraffin oil (the vapor pressure of the paraffin oil is about 0.001 atmospheres at 149° C.). However, about half of the paraffin oil content of the

4,413,110

24

gel yarns was exuded during stretching. The stretched gel yarns were extracted with TCTFE in a Soxhlet apparatus, then unwound and dried at room temperature.

In each of the examples 496-501 the spinning temperatures was 220° C., the gel concentration was 6 weight % the distance from the spinning die to the water quench was 3 inches (7.6 cm).

In examples 496 and 499-501 the diameter of each hole of the spinning die was 0.040 inches (0.1 cm). In examples 497 and 498 the hole diameters were 0.030 inches (0.075 cm). In examples 496 and 494-501 the polymer IV was 17.5. In examples 497 and 498 the polymer IV was 22.6. The other spinning conditions and properties of the final yarns were as follows:

Ex. No.	Spinning Rate cc/min-fil	Gel Fiber Take-up Speed cm/min	Stretch Temp	Stretch Ratio	Denier
496	2.02	313	140	22	206
497	1.00	310	140	12.5	136
498	1.00	310	140	15	94
499	2.02	313	120	20	215
500	2.02	313	120	22.5	192
501	2.02	313	120	20	203

Ex. No.	Tenacity g/d	Modulus g/d	% Elong
496	25	1022	3.7
497	28	1041	3.6
498	32	1389	2.8
499	30	1108	4.5
500	30	1163	4.2
501	27	1008	4.2

EXAMPLES 502-533

In the following examples a comparison is made between alternative two stage modes of stretching the same initial batch of yarn. All stretching was done in a hot tube blanketed with nitrogen.

EXAMPLE 502

GEL YARN PREPARATION

The gel yarn was prepared from a 6 weight % solution of 22.6 IV polyethylene as in example 2. The yarn was spun using a 16 hole \times 0.030 inch (0.075 cm) die.

Spinning temperature was 220° C. Spin rate was 1 cm³/min-fil. Distance from the die face to the quench bath was 3 inches (7.6 cm). Take-up speed was 308 cm/min. Nine rolls of 16 filament gel yarn was prepared.

EXAMPLES 503-576

"WET-WET" STRETCHING

In this mode the gel yarn containing the paraffin oil was stretched twice. In the first stage, three of the rolls of 16 filament gel yarns described in example 502 above were combined and stretched together to prepare a 48 filament stretched gel yarn. The first stage stretching conditions were: Stretch temperature 120° C., feed speed 35 cm/min, stretch ratio 12/1. A small sample of the first stage stretched gel yarn was at this point extracted with TCTFE, dried and tested for tensile properties. The results are given below as example 503.

25

4,413,110

The remainder of the first stage stretched gel yarn was restretched at 1 m/min feed speed. Other second stage stretching conditions and physical properties of the stretched yarns are given below.

Ex. No.	2nd Stage Stretch Temp. °C.	2nd Stage Stretch Ratio	Denier	Tenacity g/d
503	—	—	504	22
504	130	1.5	320	28
505	130	1.75	284	29
506	130	2.0	242	33
507	140	1.5	303	31
508	140	1.75	285	32
509	140	2.25	222	31
510	145	1.75	285	31
511	145	2.0	226	32
512	145	2.25	205	31
513	150	1.5	310	28
514	150	1.7	282	28
515	150	2.0	225	33
516	150	2.25	212	31

Ex. No.	Modulus g/d	% Elong	Melting* Temp. °C.
503	614	5.5	147
504	1259	2.9	—
505	1396	2.6	150, 157
506	1423	2.8	—
507	1280	3.1	—
508	1367	3.0	149, 155
509	1577	2.6	—
510	1357	3.0	—
511	1615	2.7	—
512	1583	2.5	151, 156
513	1046	3.0	—
514	1254	2.9	—
515	1436	2.9	—
516	1621	2.6	152, 160

*The unstretched xerogel melted at 138° C.

The density of the fiber of example 515 was determined to be 980 kg/m³. The density of the fiber was therefore higher than the density of a compression molded plaque and the porosity was essentially zero:

EXAMPLES 517-522

"WET-DRY" STRETCHING

In this mode the gel yarn was stretched once then extracted with TCTFE, dried and stretched again.

In the first stage, three of the rolls of 16 filament gel yarn described in Example 502 were combined and stretched together to prepare a 48 filament stretched gel yarn. The first stage stretching conditions were: stretch temperature 120° C., feed speed 35 cm/min, stretch ratio 12/1.

The first stage stretched gel yarn was extracted with TCTFE in a Soxhlet apparatus, rewound and air dried at room temperature, then subjected to a second stage of stretching in the dry state at a feed speed of 1 m/min. Other second stage stretching conditions and physical properties of the stretching yarn are given below.

Ex. sample	2nd Stage Stretch Temp. °C.	2nd Stage Stretch Ratio	Denier	Ten g/d	Mod g/d	% Elong.	Melt Temp. °C.
517	130	1.25	390	22	1193	3.0	—
518	130	1.5	332	26	1279	2.9	150, 157
519	140	1.5	328	26	1291	3.0	—
520	140	1.75	303	27	1239	2.7	150, 159
521	150	1.75	292	31	1427	3.0	—

26

-continued

Ex. sample	2nd Stage Stretch Temp. °C.	2nd Stage Stretch Ratio	Denier	Ten g/d	Mod g/d	% Elong.	Melt Temp. °C.
522	150	2.0	246	31	1632	2.6	152, 158

EXAMPLES 523-533

"DRY-DRY" STRETCHING

In this mode the gel yarn described in example 502 was extracted with TCTFE, dried, then stretched in two stages. In the first stage, three of the rolls of 16 filament yarn were combined and stretched together to prepare a 48 filament stretched xerogel yarn. The first stage stretching conditions were: stretch temperature 120° C., feed speed 35 cm/min., stretch ratio 10/1. The properties of the first stage stretched xerogel yarn are given as example 523 below. In the second stretch stage the feed speed was 1 m/min. Other second stage stretching conditions and physical properties of the stretched yarns are given below.

Ex. sample	Stretch Temp. °C.	SR	Denier	Ten g/d	Mod g/d	% Elong.	Melt Temp. °C.
523	—	—	392	21	564	4.3	146, 153
524	130	1.5	387	24	915	3.1	—
525	130	1.75	325	23	1048	2.4	150, 158
526	140	1.5	306	28	1158	2.9	—
527	140	1.75	311	28	1129	2.9	—
528	140	2.0	286	24	1217	2.3	150, 157
529	150	1.5	366	26	917	3.3	—
530	150	1.75	300	28	1170	3.0	—
531	150	2.0	273	31	1338	3.8	—
532	150	2.25	200	32	1410	2.2	—
533	150	2.5	216	33	1514	2.5	152, 156

The density of the fiber of example 529 was determined to be 940 Kg/m³. The porosity of the fiber was therefore about 2%.

EXAMPLES 534-542

MULTI-STAGE STRETCHING OF MULTI-FILAMENT YARN

In the following examples a comparison is made between two elevated temperatures stretches and a three stage stretch with the first stage at room temperature. The same initial batch of polymer solution was used in these examples.

EXAMPLE 534

UNSTRETCHED GEL YARN PREPARATION

A 6 weight % solution of 22.6 IV polyethylene yarn was prepared as in example 2. A 16 filament yarn was spun and wound as in example 502.

EXAMPLE 535

PREPARATION OF GEL YARN STRETCHED AT ROOM TEMPERATURE

The unstretched gel yarn prepared as in example 534 was led continuously from a first godet which set the spinning take-up speed to a second godet operating at a surface speed of 616 cm/min. In examples 540-542 only, the as-spun gel fiber was stretched 2/1 at room temperature in-line with spinning. The once stretched gel fiber was wound on tubes.

27

4,413,110

EXAMPLES 536-542

The 16 filament gel yarns prepared in examples 534 and 535 were stretched twice at elevated temperature. In the first of such operations the gel yarns were fed at 35 cm/min to a hot tube blanketed with nitrogen and maintained at 120° C. In the second stage of elevated temperature stretching the gel yarns were fed at 1 m/min and were stretching at 150° C. Other stretching conditions and yarn properties are given below.

Example	SR RT	SR 120° C.	SR 150° C.	Total SR	Denier	Ten g/den	Mod g/den	Elong
536	—	8.3	2.25	18.7	128	23	1510	2.6
537	—	8.3	2.5	20.8	116	30	1630	3.0
538	—	8.3	2.75	22.8	108	30	1750	2.7
539	—	8.3	3.0	24.9	107	31	1713	2.6
540	2	6.8	2.0	27.2	95	30	1742	2.5
541	2	6.8	2.25	30.6	84	34	1911	2.5
542	2	6.8	2.5	34	75	32	1891	2.2

EXAMPLES 543-551

POLYETHYLENE YARNS OF EXTREME MODULUS

The highest experimental value reported for the modulus of a polyethylene fiber appears to be by P. J. Barham and A. Keller, J. Poly. Sci., Polymer Letters ed. 17, 591 (1979). The measurement 140 GPa (1587 g/d) was made by a dynamic method at 2.5 Hz and 0.06% strain and is expected to be higher than would be a similar measurement made by A.S.T.M. Method D2101 "Tensile Properties of Single Man Made Fibers Taken from Yarns and Tows" or by A.S.T.M. Method D2256 "Breaking Load (Stength) and Elongation of Yarn by the Single Strand Method." The latter methods were used in obtaining the data reported here.

The following examples illustrate the preparation of novel polyethylene yarns of modulus exceeding 1600 g/d and in some cases of modulus exceeding 2000 g/d. Such polyethylene fibers and yarns were heretofore unknown. In the following examples all yarns were made from a 22.6 IV polyethylene, 6 weight % solution prepared as in example 2 and spun in example 502. All yarns were stretched in two stages. The first stage stretch was at a temperature of 120° C. The second stage stretch was at a temperature of 150° C. Several 16 filament yarn ends may have been combined during stretching. Stretching conditions and yarn properties are given below.

Example	Feed-1 cm/min	SR-1	Feed-2 cm/min	SR-2	Fils	Ten g/den	Mod g/den	Elong
Wet - Wet								
543	25	15	100	2.25	48	39	1843	2.9
544	35	12.5	100	2.5	64	31	1952	2.6
545	35	10.5	100	2.75	48	31	1789	2.4
546	100	6.4	200	2.85	48	27	1662	2.5
Wet - Dry								
547	25	15	100	2.0	48	36	2109	2.5
548	25	15	100	2.0	48	32	2305	2.5
549	25	15	100	2.0	48	30	2259	2.3
550	25	15	100	1.87	48	35	2030	2.7
551	25	15	100	1.95	16	35	1953	3.0

The yarns of examples 548 and 550 were characterized by differential scanning calorimetry and density measurement. The results, displayed below, indicate two distinct peaks at the melting points indicated, quite

28

unlike the broad single peak at 145.5° C. or less reported by Smith and Lemstra in J. Mat. Sci., vol 15, 505 (1980).

Ex-ample	Melt Temp(s)	Density	% Porosity
548	147, 155° C.	977 kg/m ³	0
550	149, 156° C.	981 kg/m ³	0

EXAMPLES 552-558

POLYPROPYLENE YARNS OF EXTREME MODULUS

The highest reported experimental value for the modulus of a polypropylene material (fiber or other form) appears to be by T. Williams, J. Mat. Sci. 8, 59 (1973). Their value on a solid state extruded billet was 16.7 GPa (210 g/d). The following examples illustrate the preparation of novel polypropylene continuous fibers with modulus exceeding 220 g/d and in some cases of modulus exceeding 250 g/d.

In the following examples all fibers were made from an 18 IV polypropylene, 6 weight % solution in paraffin oil prepared as in example 2. In Examples 552-556, the fibers were spun with a single hole conical die of 0.040" (0.1 cm) exit diameter and 7.5% angle. Melt temperature was 220° C. A melt pump was used to control solution flow rate at 2.92 cm³/min. Distance from the die face to the water quench was 3 inches (7.6 cm). The gel fibers were one stage wet stretched at 25 cm/min feed roll speed into a 1.5 m hot tube blanketed with nitrogen. The stretched fibers were extracted in TCTFE and air dried. Other spinning and stretching conditions as well as fiber properties are given below.

Example	Gel Fiber Take-up Speed	Stretch Temp °C.	SR	Denier	Ten g/d	Mod g/d	Elong
---------	-------------------------	------------------	----	--------	---------	---------	-------

552	432	139	10	33	13.0	298	15.8
553	432	138	10	34	13.0	259	18.3

29

4,413,110

-continued

Example	Gel Fiber Take-up Speed	Stretch Temp °C.	SR	Denier	Ten g/d	Mod g/d	Elong
554	317	140	5	45	11.2	262	19.9
555	317	140	10	51	11.0	220	19.6
556	317	150	10	61	8.8	220	29.8

The fiber of example 556 determined by differential scanning calorimetry to have a first melting temperature of 170°-171° C. with higher order melting temperatures of 173° C., 179° C. and 185° C. This compares with the 166° C. melting point of the initial polymer. The moduli of these fibers substantially exceed the highest previously reported values.

In Examples 557 and 558, the yarns were spun with a 16 hole \times 0.040 inch (1 mm) capillary die. The solution temperature was 223° C., and the spinning rate was 2.5 cm³/min-filament. The distance from the die face to the water quench bath was 3 inches (7.6 cm). Take-up speed was 430 cm/min. The gel yarns were "wet-wet" stretched in two stages. The first stage stretching was at 140° C. at a feed speed of 35 cm/min. The second stage stretching was at a temperature of 169° C., a feed speed of 100 cm/min and a stretch ratio of 1.25/1. Other stretching conditions as well as fiber properties are given below.

Ex- ample	SR-1	Denier	Ten g/den	Mod g/den	% Elong.
557	9.5	477	10	368	6.8
558	9.0	405	10	376	5.7

The moduli of these yarns very substantially exceed the highest previously reported values.

We claim:

1. A stretched polyethylene fiber of substantially indefinite length being of weight average molecular weight at least about 500,000 and having a tenacity of at least about 20 g/denier, a tensile modulus at least about 500 g/denier, a creep value no more than about 5% (when measured at 10% of breaking load for 50 days at 23° C.), a porosity less than about 10% and a main melting temperature of at least about 147° C. (measured at 10° C./minute heating rate by differential scanning calorimetry).

2. The stretched polyethylene fiber of claim 1 having a tenacity of at least about 30 g/denier and a tensile modulus of at least about 1000 g/denier.

3. The stretched polyethylene fiber of claim 2 having a tensile modulus of at least about 1600 g/denier.

30

4. The stretched polyethylene fiber of claim 2 having a tensile modulus of at least about 2000 g/denier.

5. The stretched polyethylene fiber of claim 1 or 2 having a main melting temperature at least about 149° C. (measured at 10° C./minute heating rate by differential scanning calorimetry).

6. The stretched polyethylene fiber of claim 1 or 2 or 3 or 4 having a main melting temperature of at least about 149° C. (measured at 10°/minute heating rate by differential scanning calorimetry).

7. The stretched polyethylene fiber of claim 1 or 2 or 3 or 4 being of weight average molecular weight of at least about 1,000,000.

8. The stretched polyethylene fiber of claim 1 or 2 or 3 or 4 being of weight average molecular weight between about 2,000,000 and about 8,000,000.

9. A stretched polyethylene fiber of substantially indefinite length being of weight average molecular weight of at least about 1,000,000 and having a tensile modulus of at least about 1600 g/denier, a main melting temperature of at least about 147° C. (measured at 10° C./minute heating rate by differential scanning calorimetry) and an elongation-to-break of not more than 5%.

10. The stretched polyethylene fiber of claim 9 being of weight average molecular weight between about 2,000,000 and about 8,000,000.

11. The stretched polyethylene fiber of claim 9 or 10 having a main melting temperature of at least about 149° C. (measured at 10° C./minute heating rate by differential scanning calorimetry).

12. The stretched polyethylene fiber of claim 9 or 10 having a tensile modulus of at least about 2000 g/denier.

13. A stretched polypropylene fiber of substantially indefinite length being of weight average molecular weight of at least about 750,000 and having a tenacity of at least about 8 g/denier, a tensile modulus of at least about 160 g/denier and a main melting temperature of at least about 168° C. (measured at 10° C./minute heating rate by differential scanning calorimetry).

14. The stretched polypropylene fiber of claim 13 having a tenacity of at least about 11 g/denier.

15. The stretched polypropylene fiber of claim 13 having a tenacity of at least about 13 g/denier.

16. The stretched polypropylene fiber of claim 13 having a tensile modulus of at least about 200 g/denier.

17. The stretched polypropylene fiber of claim 13 having a tensile modulus of at least about 220 g/denier.

18. The stretched polypropylene fiber of claim 13 or 14 or 15 or 16 or 17 being of weight average molecular weight at least about 1,000,000.

19. The stretched polypropylene fiber of claim 13 or 14 or 15 or 16 or 17 being of weight average molecular weight between about 2,000,000 and about 8,000,000.

* * * * *

55

60

65

BROOKSTEIN DECLARATION EXHIBIT 12

LOGY

TEXTILE SCIENCE AND TECHNOLOGY 6

PRODUCTION AND APPLICATIONS OF POLYPROPYLENE TEXTILES

by Oldřich Pajgrt
Bohumil Reichstädter
and František Ševčík

Wool Research Institute, Brno, Czechoslovakia



ELSEVIER SCIENTIFIC PUBLISHING COMPANY

AMSTERDAM OXFORD NEW YORK 1983

lene fibres appear as extruded fibres have

h a heated stage the polyene fibres melt at y can be distinguished melt in the range of

than water. This fact lends with other fibres fibre blend is cut into are then loosened and surface active agent. ylene polymer and can ng point, as described

fibres shrink and melt ile still in flame, burn s blown out, an odour d.

ic blends quantitatively,

stituting the blend are and also polyethylene) tures below 100 °C and with polypropylene/wool 15 % solution of NaOH ylene/cotton blends the blend in a 75 % H₂SO₄

ed from the fibre blend l at 146 °C. The exact Gralinski [39]. that no foreign substance , that various oils, sizes,

textile finishing aids, antistatic agents and others have been removed. In some cases it suffices to treat the blend in distilled water (removal of water-soluble sizes, salts and soaps), while in some others a solvent extraction, using e.g. diethyl ether, chloroform or petroleum ether, should be used in order to remove oils and greases. In removing a formaldehyde-based resin it is recommended to hydrolyze the fibre blend in a boiling 0.02 N HCl under reflux at the fibre-to-liquor ratio of 1 : 100 for 1 hour. The fibre blend is then rinsed to give a neutral reaction.

2.3.3 Important physical and mechanical properties of polypropylene fibres

2.3.3.1 Specific volume, density, covering power, appearance and fineness

Polypropylene fibres made of isotactic polymer have a density in the range of 0.90-0.91 g cm⁻³; the fibres are therefore lighter than water. They have practically the highest specific volume, thus giving also the highest covering power of all common textile fibres.

Some characteristics in this respect for most commercial textile fibres are compared in Table 6. The cross-sectional area given here has been calculated under the presumption that all the fibres have a 0.11 tex fineness and a circular cross-section.

Table 6 — Specific parameters of fibres

Fibre	Density [g cm ⁻³]	Specific volume [cm ³ g ⁻¹]	Cross-sectional area [μm ² tex ⁻¹]	[%]
Polypropylene	0.92	1.09	1087	100
Nylon	1.14	0.88	877	81
Acrylic	1.18	0.85	847	78
Polyester	1.38	0.72	725	67
Wool	1.32	0.76	756	70
Cotton	1.50	0.67	667	65
Viscose rayon	1.52	0.66	658	60

From the table it can be derived that the polypropylene fibre gives better cover than nylon, acrylic and polyester fibres by 19, 22 and 33 %, respectively. And when compared with viscose rayon, this difference reaches as much as 40 % in favour of polypropylene.

In other words, when different fibres of the same covering power and, necessarily, of different fineness are used in making comparable

fabrics, the fabrics in theory are lighter or heavier according to what fibres are constituting them.

To give an example on the cover equivalence, some fibres of the same covering power as a 0.33 tex polypropylene fibre are ranked as follows:

- 0.42 tex nylon fibre
- 0.43 tex acrylic fibre
- 0.46 tex triacetate or polyvinylalcohol fibre
- 0.50 tex polyester or polyvinylchloride fibre
- 0.55 tex viscose rayon fibre
- 0.78 tex polytetrafluoroethylene fibre
- 0.90 tex glass fibre

It follows from the above comparison that, in theory, a knitted or woven fabric made of glass fibre is about three times heavier than that made of polypropylene fibre provided, of course, that the fabrics are of equal construction in order to be comparable.

The given data can be used as a guide only with simple fibres, monofilaments and tapes; with multifilaments and spun yarns a correction should be taken into account due to the porosity.

Appearance and fineness of polypropylene fibres

Polypropylene fibres are white and can vary from lustrous and semi-translucent to dull and opaque in appearance, depending on the amount of delustrant added to the polymer. They can also be dope-dyed in various shades of high fastness.

The fibres have a waxy-to-soapy handle and a smooth, uniform surface, and are mostly circular in cross-section, though some other cross-sectional shapes are also available. They are produced in the fineness ranging from 0.11 to 2.2 tex.

2.3.3.2 Tensile properties

Polypropylene fibres are produced in different forms, such as staple, monofilament, multifilament and low- and high-denier tows, and are modified to suit a particular textile or technical end-use. From the viewpoint of tensile properties they can be divided into the following three groups:

Fibres with a medium tenacity of 400 – 600 mN tex⁻¹

These are the main fibres produced and used most commonly, both as staple and as filament.

avier according to what

, some fibres of the same
e are ranked as follows:

Fibres with a high tenacity of 900–1300 mN tex⁻¹

→ The fibres are intended for special, technical and military uses and are produced as staple, filament and low-denier tow.

Fibres with a low tenacity of 200±300 mN tex⁻¹

→ Staple fibres of this kind are used to advantage in the production of carpet yarns, bestowing on the yarns a high resiliency at the expense of strength. Nevertheless, the strength of the yarns is still sufficient for the purpose. They are commercially produced under such trade names as Meraklon SR and Meraklon DR. ←

The loop and knot strengths are lower by some 10–20 % than the tensile strength. The moisture regain at 21 °C and 65 % R.H. is below 0.1 % and this is why the fibre tenacity remains practically unaltered even after the fibres have been wetted, boiled or steamed for a long time.

Elongation

On average, the elongation varies according to the fibre form as follows:

- monofilament 15–30 %
- multifilament 20–80 %
- normal-tenacity staple 20–35 %
- low-tenacity staple 70–100 %
- Meraklon SR 70–90 %
- Meraklon DR 70–100 %

Load-elongation curves, obtained under standard conditions, for some fibres are shown in Fig. 24. From it a comparison can be made of some kinds of polypropylene fibres including filament, standard staple (Meraklon S, cotton-type) and low-tenacity staple (Meraklon SR, carpet-type), and other commercially important fibres.

2.3.3.3 Elastic properties

Elastic properties of polypropylene fibres can vary along with other mechanical properties in a wide range of values. They depend on the type of polymer and technological conditions in spinning, drawing and preparation, as well as on the technology of textile processing and, in particular, physical and chemical treatments.

To give an example, the elastic recovery at different elongations for a Vectra polypropylene fibre is mentioned briefly below. Both high- and medium-tenacity types of this fibre show comparable elastic recovery giving

at 5 % elongation 80 % instant recovery and no residual deformation,
at 10 % elongation 95 % elastic recovery and 5 % residual deformation,

at 15 % elongation 90 % elastic recovery and 10 % residual deformation,
at 20 % elongation 17.5 % residual deformation.

The fibre exhibiting a very low tenacity of 200 mN tex^{-1} , produced under special conditions at high temperature, gives at 50 % elongation an instant elastic recovery of 95 % and recovers completely after 5 minutes.

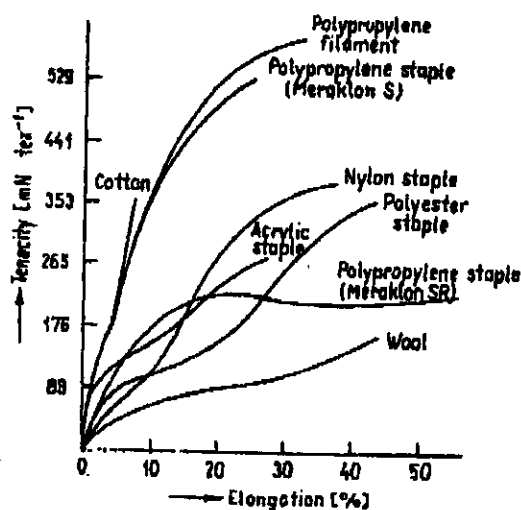


Fig. 24. Load-elongation curves for some fibres

In terms of elasticity polypropylene fibres are ranked below nylons. It should be pointed out that the recovery, and the secondary recovery in particular, of medium-tenacity polypropylene fibres is fairly slow and, in practice, the fibres are considered as only slightly lively.

2.3.3.4 Thermal properties and light exposure

Melting point: about $160-175^{\circ}\text{C}$.

Softening point: about $140-150^{\circ}\text{C}$.

Heat conductivity: $11.7 \times 10^{-14} \text{ J cm}^{-1} \text{ s}^{-1} \text{ K}^{-1}$.

Specific heat: $1.9 \text{ J g}^{-1} \text{ K}^{-1}$.

Polypropylene fibres show the lowest heat conductivity and, consequently, the highest insulating capacity of all commercial fibres. As for the heat conductivity, given as a relative index against air, some fibres in this respect are compared in Table 7.

and 10% residual de-

ion.

00 mN tex⁻¹, produced
ives at 50% elongation
mpletely after 5 minutes.

Table 7 -- Heat conductivity of some
textile fibres

Fibre	Index
(Air)	1.0
Polypropylene	2.8
Polyvinylchloride	6.4
Wool	7.4
Acetate	8.6
Viscose rayon	11.0
Cotton	17.5

At -40 °C the fibre preserves its flexibility and shows a higher tenacity and a somewhat lower elongation than at 20 °C. With the increasing temperature the fibre tenacity reduces, as shown in Fig. 25.

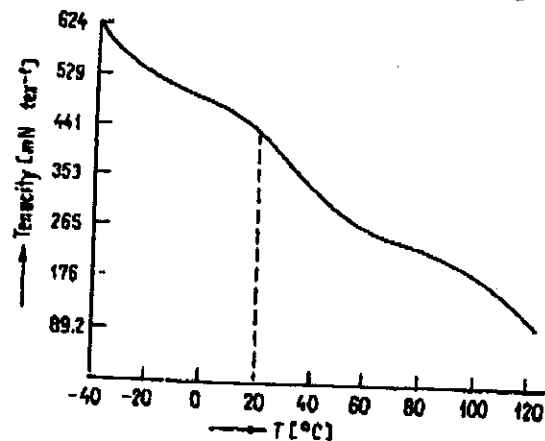


Fig. 25. Effect
of temperature
on the tenacity
of polypropylene fibres

The fibre loses strength gradually with increases in temperature up to the point of softening. At the same time its elongation becomes somewhat higher and the course of the load-elongation relation changes. The zero strength is in the range of 160–165 °C. Heat-setting should be effected at about 130–135 °C.

Under excessive heat the fibre melts forming a molten droplet. In naked flame it melts and burns, and, detached from the flame, it extinguishes itself or burns only slowly. From the viewpoint of flammability the fibre behaviour is typical of polyolefine fibres.

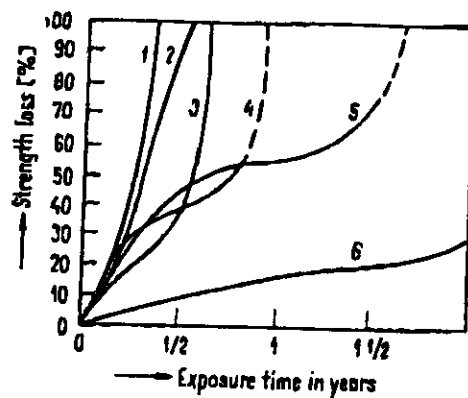


Fig. 26a. Time curves of the resistance of fibres exposed to natural weather conditions for two years in Wilmington in the U.S.A.

1 — silk, 2 — viscose rayon, 3 — acetate, 4 — cotton, 5 — Cordura viscose rayon, 6 — acrylic (Orlon)

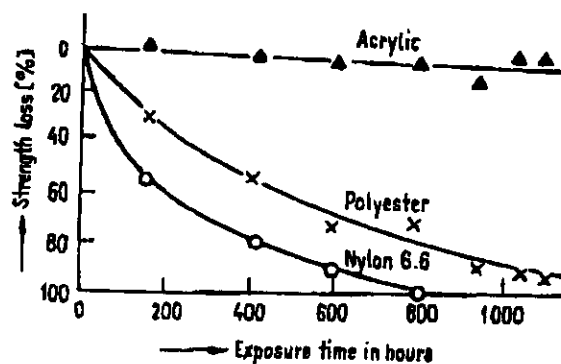


Fig. 26b. Resistance of acrylic, polyester and nylon 6.6 fibres to sunlight

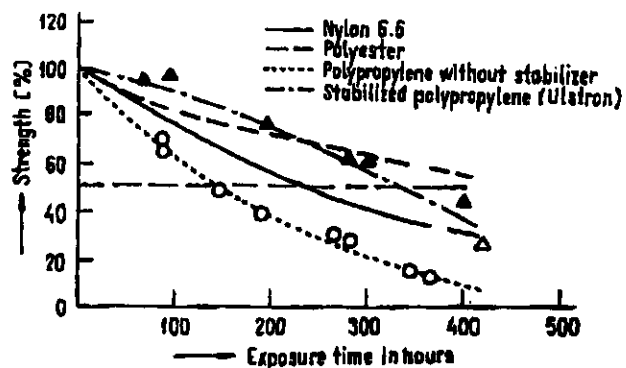
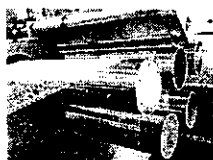


Fig. 26c. Resistance of polyester, nylon 6.6 and polypropylene fibres to weathering in South Florida in the U.S.A.

BROOKSTEIN DECLARATION EXHIBIT 13

Shakespeare, a world leader and producer of specialty monofilaments and polymers.


[Home](#)
[Contact Us](#)
[Site Map](#)


Specialty/High Performance Monofilaments

- [About Us](#)
- [Sales Organization](#)
- [Events](#)
- [Documentation](#)
- [Products](#)
- [Employment](#)
- [NEWS](#)

PVDF Monofilament: Polyvinylidene Fluoride.

Composition:

- Melt Point = 174°C (345°F)
- Density = 1.78g/cc

Attributes:

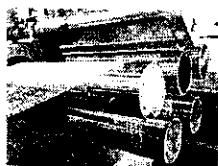
- Outstanding resistance to weathering/UV exposure
- Outstanding chemical resistance
- Excellent soil release (low surface energy)
- Low coefficient of friction
- Lowest moisture regain
- High continuous use temperature (150 °C)
- Inherent Flam Resistance

Typical Properties- Trial Lots	MX229
Diameter	0.015
Denier	1850
Tensile Strength (lbs)	19.18
Tenacity (gdp)	4.71
Elongation at Break (%)	17.62
Loop Strength (lbs)	7.19
Loop Tenacity (gdp)	1.76
Loop Elongation (%)	5.5
Loop Impact Strength (ft-lbs/in)	70 (678g wt)
Common Knot Strength (lbs)	8.06
Common Knot Tenacity (gdp)	1.98

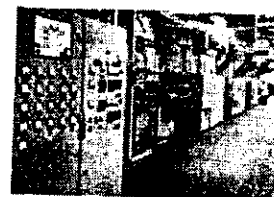
Common Knot Elongation (%)	11.4
Free Shrinkage at 132 °C/10 mins (%)	16.3
Boiling Water Shrinkage/5 mins (%)	9.13

[About Us](#) | [Sales](#) | [Events](#) | [Products](#) | [Documents](#) | [Employment](#) | [News](#) | [Disclaimer](#)

Shakespeare, a world leader and producer of specialty monofilaments and polymers.

[Home](#)[Contact Us](#)[Site Map](#)

Polyolefin Monofilaments



- [About Us](#)
- [Sales Organization](#)
- [Events](#)
- [Documentation](#)
- [Products](#)
- [Employment](#)
- [NEWS](#)

General Characteristics: Generally good chemical resistance. Good biological resistance.

Standard Products	Type	Breaking Strength*		Shrinkage in boiling water, %
		GPD	KPSI	
MX-201	PP	4.0	46	11
MX-200	PP	3.0	35	6
MX-305	HDPE	4.2	50	12
MX-306	LDPE	1.7	21	57

PP = Polypropylene

HDPE = High Density Polyethylene

LDPE = Low Density Polyethylene

*GPD - Grams per denier

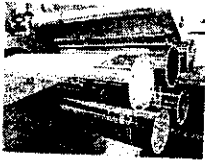
KPSI = Thousand pounds per square inch

[About Us](#) | [Sales](#) | [Events](#) | [Products](#) | [Documents](#) | [Employment](#) | [News](#) | [Disclaimer](#)

Shakespeare, a world leader and producer of specialty monofilaments and polymers.


[Home](#)
[Contact Us](#)
[Site Map](#)


Polyester Monofilaments



- [About Us](#)
- [Sales Organization](#)
- [Events](#)
- [Documentation](#)
- [Products](#)
- [Employment](#)
- [NEWS](#)

General Characteristics: Dimensionally stable, low moisture regain. Good UV and biological resistance.

Hydrolytically Stabilized Polyester: Specifically formulated to resist degradation caused by hot, moisture environments.

Sizes, shapes, colors...

Our monofilaments are available in a wide variety of shapes, colors and sizes depending on polymer types.

Various spool types are also available.

Standard Products	Breaking Strength*		Shrinkage at 200 °C, %
	GPD	KPSI	
<u>WP-550</u>	4.5	80	6.5

Standard Polyester: For applications not requiring hydrolytic stability.

Standard Products	Breaking Strength*		Shrinkage at 200 °C, %
	GPD	KPSI	
<u>WP-104</u>	4.5	80	3
<u>WP-120</u>	4.5	80	3
<u>WP-200</u>	6.0	107	15
<u>WP-320</u>	6.0	107	20

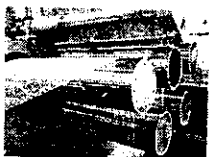
Superior abrasion resistant products.

*GPD - Grams per denier

KPSI = Thousand pounds per square inch

[About Us](#) | [Sales](#) | [Events](#) | [Products](#) | [Documents](#) | [Employment](#) | [News](#) | [Disclaimer](#)

Shakespeare, a world leader and producer of specialty monofilaments and polymers.


[Home](#)
[Contact Us](#)
[Site Map](#)


Nylon Monofilaments

- [About Us](#)
- [Sales Organization](#)
- [Events](#)
- [Documentation](#)
- [Products](#)
- [Employment](#)
- [NEWS](#)

General Characteristics: Tough, abrasion resistant.

Nylon 6: Flexible, resilient, resists compaction.

*GPD - Grams per denier
KPSI = Thousand pounds
per
square inch

Standard Products	Breaking Strength*		Shrinkage at 175 °C, %
	GPD	KPSI	
<u>WN-18</u>	6	88	6.5
<u>WN-250</u>	5.5	81	18
<u>NX-1037*</u>	5.5	81	6.5

* Low monomer for wet environments

Nylon 6,10: Low moisture regain. Increased chemical resistance. Improved dimensional stability.

Standard Products	Breaking Strength*		Shrinkage at 175 °C, %
	GPD	KPSI	
<u>WN-50</u>	4.5	63	5
<u>NX-201</u>	5.5	76	12

Nylon 6,6: Higher operating temperature range.

Standard Products	Breaking Strength*		Shrinkage at 175 °C, %
	GPD	KPSI	
<u>WN-101</u>	4.5	66	4
<u>WN-125</u>	5.5	81	3

NX-301	5.0	74	12
--------	-----	----	----

Both WN-125 and NX-301 are produced from a heat stabilized, high molecular weight polymer which increases heat and abrasion.

About Us | Sales | Events | Products | Documents | Employment | News | Disclaimer

BROOKSTEIN DECLARATION EXHIBIT 14

VILENE* - A MONOFILAMENT OF POLYVINYLIDENE FLUORIDE

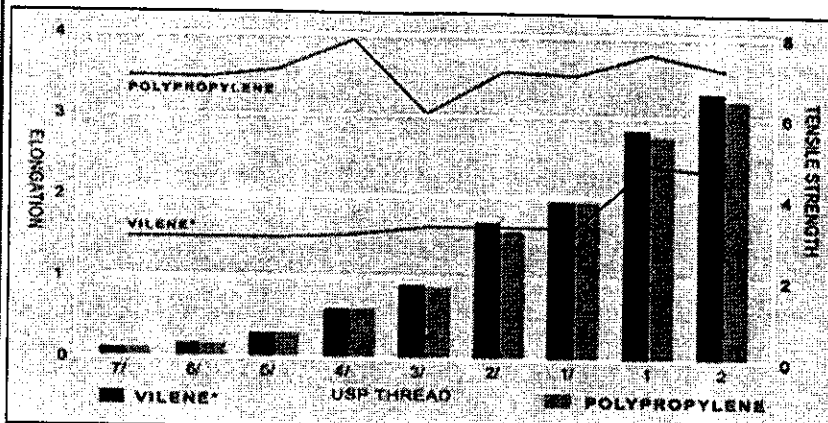
◀ BACK × HOME

Menu:

Main Pages
Fineline* Cutting
Reverse Cutting
Reverse Premium Cutting
Round Bodied Taper
A-Cute Taper*

♦ MONOFILAMENT P.V.D.F.

VILENE* is a monofilament of Polyvinylidene Fluoride (PVDF) which is non-absorbable physiologically inert. Maintaining it's tensile strength in situ, Vilene provides superior clinical security to the Surgeon. Combining the high tensile strength and low elongation (see chart below) excellent handling and knotting properties.



NOTES

1. Standard knot pull European Pharmacopoeia, US Pharmacopoeia, Viscous absorbable sutures (for non-sterile suture)

2. Standard knot pull a simple knot.

3. Elongation is the percentage of material at break or rupture pull test expressed as the original length.

Experience has shown that Vilene* has excellent security. The springiness that affects all monofilaments when removed from the packaging is taken out by a gentle pull. It can be used in all procedures where polypropylene monofilament is utilised. Unlike polypropylene which after sterilisation is waxy in feel and is prone to fray, Vilene* is smooth, fray free and supple. Vilene* is sterilised by gamma irradiation. CV 300 need cardiovascular sutures use a CV300 needle giving the Surgeon optimum performance with suture material and needle.

Knotting:

As with all synthetic non-absorbable sutures, knot tying requires the standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstance.

Vilene is available on the following needles:

- ♦ Fineline Cutting
- ♦ Reverse Cutting
- ♦ Reverse Premium Point Cutting
- ♦ Round Bodied Taper
- ♦ Round Bodied A-Cute Taper

Both single & double armed sutures are available.

▲ TOP

[COPYRIGHT NOTICE | DYNEK SUTURES PRIVACY AND MAIL LIST POLICIES]
Content ©1998-2004 Dynek Pty. Ltd. - ACN 007 758 465 - 9 Circuit Drive, HENDON, 5014 AUSTRALIA
Ph: (+61 8) 8268 2033 Fax: (+61 8) 8347 0434 - E-mail: cservice@dynek.com.au

BROOKSTEIN DECLARATION EXHIBIT 15

CE
0085



FiberWire™

IMPORTANT PRODUCT INFORMATION WICHTIGE PRODUKTINFORMATION NOTICE D'UTILISATION IMPORTANTE IMPORTANTI INFORMAZIONI PER L'USO INSTRUCCIONES IMPORTANTES PARA EL USO

Tel: +49 81 31 59 57 0 • Fax: +49 81 31 59 57 63



DU-0085
Rev. 3

Description:

Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The Arthrex FiberWire may also be sold with needles attached (designed to be used in a variety of sizes). The suture is made of polyethylene fibers and polyester fiber braided, separated and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue. The Arthrex FiberWire is available non-tyed (knotless) or tied in knots or excesses (U.S.P. and European standards (except for diameter)).

Indications:

Arthrex FiberWire is indicated for use in soft tissue separation and or ligation. FiberWire is not for use in cardiac indications.

Actions:

Arthrex FiberWire, when tested per ISO 10993, Biological Evaluation of Medical Devices - Part 12: Tests for Irritation and Sensitization, had no reactions of allergic or sensitive nature. The dyed suture and coating are pharmacologically inactive.

Arthrex FiberWire is not absorbed, but may become encapsulated in the surrounding connective tissues. The Arthrex FiberWire is not known to have significant change in tensile strength in vivo.

Contraindications:

None known

Warnings:

Do not re-sterilize. Once open, discard unused suture. Do not expose to heat.

Manufacturer:
Arthrex Inc.
Naples, Florida 34108-1945 • U.S.A.
Tel-Fax: +1 800 334-4404
www.arthrex.com

E.C. Representative:
Arthrex Med. Inst. GmbH
65757 Karlshof
Germany

As with any foreign body, prolonged contact of this or any other suture with soft tissues, such as those found in the urinary or biliary tracts, may result in calcific formations. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions:

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Assure that all ends have been secured using accepted surgical knot tying techniques. Adequate knot security requires the accepted surgical technique of full, square ties, with additional throws as warranted by surgical circumstances and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilament. Care should be taken to prevent damage to surrounding

Issue or user procedure due to improper handling of the needlepoint.

Do not grasp the needle at the point or attempt to exert damage to these areas. Reheating needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in "sharp" containers.

Adverse Reactions:

Adverse reactions have not been noted with the Arthrex FiberWire product in animal testing. Common non-absorbable suture reactions may include wound dehiscence, cuticle formation in urinary and biliary tracts when prolonged contact with soft solutions such as urine and bile occurs, enhanced bacterial infection, minimal acute inflammatory tissue reaction, pain, edema, and erythema at the wound site. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Sterilization:

Arthrex FiberWire suture is supplied sterile. Method of sterilization: EO

Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

Storage Conditions:

Store below 25°C, away from moisture and direct heat. Do not use after expiration date.

How Supplied:

The Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture except diameter). The suture is supplied sterile in pre-cut lengths and in some cases with tapered needles. The Arthrex FiberWire is available in non-tyed (knotless) or dyed colors. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.

SYMBOLS USED ON LABELING

Do not reuse

STERILE EO Suture under the packaging is damaged or open. Method of sterilization: EO

STERILE R Suture under the packaging is damaged or open. Method of sterilization: gamma radiation

Latex free

See package insert

Use by: year

8 months

Beschreibung:

Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nadelmaterial entspricht dem USP-Normen für Nadeln), mit Ausnahme des Durchmessers). Arthrex FiberWire ist unter Umständen auch mit an das Fadenende angehängten (sicherheitsgeschweißten) Nadeln unterschiedlicher Größen erhältlich. Das Nadelmaterial besteht aus polyethylen, separiert und für das Durchdringen durch Gewebe beschichtet. Die Fäden bestehen aus Polyethylen und Polyesterfasern, die miteinander verdreht sind und das Durchdringen durch Gewebe erleichtern. Die Beschichtung wirkt als Gleitmittel für das Durchdringen durch Gewebe. Das Arthrex FiberWire ist ungetriggert (knotlos) oder getriggert (knotlos oder überschüssige U.S.P.- und europäische Standards (mit Ausnahme des Durchmessers)).

Anwendungsgebiete:

Arthrex FiberWire ist für Weichteilseparation und/oder -ligatur vorgesehen. FiberWire nicht für kardiale Indikationen verwenden.

Funktionen:

Tests bei Arthrex FiberWire gemäß ISO 10993, Biologischer Evaluation of Medical Devices - Part 12: Tests for Irritation and Sensitization, ergaben keine allergischen oder empfindlichen Reaktionen. Das gefärbte Nadelmaterial und die Beschichtung sind pharmakologisch inaktiv.

Arthrex FiberWire wird zwar nicht absorbiert, jedoch kann Umkapselung von umgebenden Bindegewebsanteilen, bei Arthrex FiberWire wurde in vivo keine signifikante Änderung der Zugsfestigkeit festgestellt.

Gegenanzeigen:

Unbekannt

Warnhinweise:

Nicht resterilisieren. Unbenutztes Fadenmaterial nicht dem Offenen ausliefern. Vor Hitze warnen.

Benutzer sollten vor dem Verschieben von Wunden mit Arthrex FiberWire mit den chirurgischen Präparations-Techniken vertraut sein. Bei denen nicht-überwachten Fäden verwendet wird, die das Durchdringen in nach Anwendungsstelle und verwendetem Fadenmaterial unterschiedlich ist.

Wie bei Fremdörpern aller Art kann der längere Kontakt dieses oder jedes anderen Fadenmaterials mit Schutzorganen, (wie z.B. im Harn- und Gallenkanal) vorhanden sind) zu Calculusbildung führen. Bei der Drainage und beim Schließen von Infektionen oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Vorsichtsmaßnahmen:

Bei der Handhabung dieses oder jedes anderen Fadenmaterials sorgfältig darauf achten, dass das Material nicht beschädigt wird. Vermeiden Sie das Verformen oder das Anfeuchten mit chirurgischen Instrumenten wie Zangen oder Nadeln nach Möglichkeit vermeiden.

Sicherstellen, dass sämtliche Knoten gemäß den akzeptierten chirurgischen Knotenbindungspraktiken sicher befestigt wurden. Voraussetzung für angemessene Knotensicherheit ist die Verwendung von festen, qualitativ hochwertigen Scherfen mit zusätzlichen Verankerungen, je nach chirurgischer Situation und Erfahrung des

Chirurgen. Besonders beim Verfügen von monofilen Fäden ist eine Umständlichkeit zu vermeiden, um Schäden am umgebenen Gewebe und Beschädigung der Wunde zu vermeiden. Handhabung des Nadelspitzen zu vermeiden.

Das Nadelmaterial der Spitze oder am Gelenk festhalten, um das Durchdringen durch Gewebe zu erleichtern. Nach dem Durchdringen durch Gewebe in stabile Wunden und bei der Drainage und beim Schließen von Infektionen oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Nebenwirkungen:

Bei Tierversuchen wurden bei der Verwendung von Arthrex FiberWire keine Nebenwirkungen festgestellt. Zu den bei nicht-absorbierbarem Faden üblichen Reaktionen zählen unter Umständen Drainage, Calculusbildung in Harn- und Gallenwegen bei längerem Kontakt mit Sekretionsorganen (wie sie im Urin und in der Gallenblase vorhanden sind), verstärkte Bakterieninfektion, minimale akute Gewebeschädigungen, Schmerzen, Ödem und Erythem an der Wundstelle. Vereinzelt wurden Schichten mit kontaminierten chirurgischen Nadeln kann zur Übertragung von Blutpathogenen führen.

Stabilität:

Arthrex FiberWire wird nicht gealtert. Nicht resterilisieren. Bei beschädigter oder zuvor geöffneter Packung nicht verwenden. Offenes, unbenutztes Fadenmaterial entsorgen.

Lagerungsbedingungen:

Unter 25°C trocknen und fern von direkter Hitzeinwirkung lagern. Nicht nach dem Verfallsdatum verwenden.

Literatur:

Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich. Das Nadelmaterial entspricht dem USP-Normen für Nadeln, mit Ausnahme des Durchmessers. Das Fadenmaterial ist unter Umständen auch mit an das Fadenende angehängten (sicherheitsgeschweißten) Nadeln unterschiedlicher Größen erhältlich. Das Nadelmaterial besteht aus polyethylen, separiert und für das Durchdringen durch Gewebe beschichtet. Die Fäden bestehen aus Polyethylen und Polyesterfasern, die miteinander verdreht sind und das Durchdringen durch Gewebe erleichtern. Die Beschichtung wirkt als Gleitmittel für das Durchdringen durch Gewebe.

AUF DER VERPACKUNG VERWENDETE SYMBOLE

Nicht wiederverwenden

STERILE EO Suture unter der Verpackung ist beschädigt oder offen. Method of sterilization: EO

STERILE R Suture unter der Verpackung ist beschädigt oder offen. Method of sterilization: gamma radiation

Latexfrei

See package insert

Verwendbar bis: Jahr und Monat

BROOKSTEIN DECLARATION EXHIBIT 16

TO : Arthrex

ATTN: Don Grafton

FROM : Brian Hallett

DATE : 19/10/2000

SUBJECT : Polyester - Dyneema Braid

Dear Don,

Please find enclosed 4 DT trials samples for your inspection ,these have been made using Polyester/Dyneema mixed either in the cover or straight core, to match US2 I have set out below a matrix of how each was made and their results for your information

DT PA23 SAMPLE COMMENTS: CORE DID NOT BREAK ON KNOT PULL ONLY COVER, STRAIGHT PULL CORE BROKE COVER STAYED INTACT.

16 Carrier m/c

COVER 16 carriers in use each with 1 end of 138 d'tex Polyester per carrier

CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)

PPI 38

Stage	St/pull kg	Knot/pull kg	Runnage mt/kg	Diameter mm	Extensin %	Solids %
M/c	19.12	9.87	3455	0.677	5.48	
Dye	17.05	8.81		0.589	10	
Stretch	16.51	6.95		0.577	5.3	15.3
Finish	17.2	10.35	3375	0.569	6.8	

DEPUY MITEK
EXHIBIT 164
04cv12457

PR 06515
Confidential - Outside Attorneys' Eyes Only

DT PA25 SAMPLE COMMENTS: BOTH CORE AND COVER BROKE ON THE STRAIGHT PULL AT DYE STAGE, ON THE STRAIGHT PULL AT STRETCH STAGE THE CORE BROKE ONLY

16 Carrier m/c

COVER 16 carriers in use

8 car with 1 end of 113 poly 8 car with 1 end of 110 dyneema

CORE 1 end of 190/1/3 with 10 TPI "S" and 7 TPI "Z"

PPI 50

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	28.82	11.293	3803	0.582	11.15	
Dye	25.56	10.5		0.582	14.7	
Stretch at 5%	26.84	10.58		0.587	9.9	15.3
Finish	24.35	11.95	3703	0.55	11.2	

DT PA26 SAMPLE COMMENTS: CORE BROKE IN FIRST TWO READINGS, WHOLE BRAID BROKE IN THIRD

16 Carrier m/c

COVER 16 carriers in use

8 car with 1 end of 113 polyester 8 car with 1 end of 110 Dyneema

CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)

PPI 50

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	21.82	10.953	3908	0.681	5.28	
Dye	23.62	12.26		0.693	10.1	
Stretch at 5%	24.56	11.79		0.573	5.8	15.3
Finish	21.48	12.87	3786	0.578	6	

DT PA27 SAMPLE COMMENTS: CORE DID NOT BREAK ON KNOT PULL ONLY COVER, STRAIGHT PULL CORE BROKE COVER STAYED INTACT.

16 Carrier m/c

COVER 16 carriers in use

16 car with 1 end of 113 Polyester per carrier

CORE 1 end of 165/1/3 with 10 TPI "S" and 7 TPI "Z"(Dyneema)

PPI 44

Stage	St/pull kg	Knot/pull kg	Runnage m/kg	Diameter mm	Extensin%	Solids %
M/c	19.14	9.037	4033	0.549	5.9	
Dye	16.18	8.35		0.548	8.5	
Stretch at 5%	16.49	6.54		0.545	5.5	15.3
Finish	16.12	8.04	3919	0.553	5.6	

If I can be any further assistance please do not hesitate to contact me

Kind regards

Brian Hallett

Brian Hallett

Product Development Manager

PR 06514

Confidential - Outside Attorneys' Eyes Only

BROOKSTEIN DECLARATION EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

DEPOSITION OF:

ASHLEY HOLLOWAY

DATE:

September 15, 2005

TIME:

1:08 p.m. to 5:07 p.m.

LOCATION:

The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY:

Plaintiff

REPORTER:

Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER:

Les Smoak, CLVS

<p>1 suture --</p> <p>2 A. Correct.</p> <p>3 Q. -- with respect to knot security; is that right?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. Does Arthrex test its FiberWire sutures</p> <p>6 for pliability?</p> <p>7 A. No.</p> <p>8 Q. Do you know what pliability means?</p> <p>9 A. Pliability --</p> <p>10 Q. As it relates to FiberWire sutures?</p> <p>11 A. I don't know the exact definition, no.</p> <p>12 Q. But Arthrex does not test its FiberWire sutures</p> <p>13 for pliability?</p> <p>14 A. No.</p> <p>15 Q. Has it ever tested its FiberWire sutures for</p> <p>16 pliability?</p> <p>17 A. Not that I'm aware of.</p> <p>18 Q. Does Arthrex test its FiberWire sutures for</p> <p>19 handleability?</p> <p>20 A. Yes.</p> <p>21 Q. How does Arthrex test its FiberWire sutures for</p> <p>22 handleability?</p> <p>23 A. It's a subjective test.</p> <p>24 Q. What do you mean by that?</p> <p>25 A. I mean basically we give a piece of suture to a</p>	<p>30</p> <p>1 Q. What do you mean by that?</p> <p>2 A. I mean everything that's in that construct.</p> <p>3 Q. Contributes to the handleability of the suture?</p> <p>4 A. Yes.</p> <p>5 Q. What is the handleability of Arthrex's FiberWire</p> <p>6 suture?</p> <p>7 MR. TAMBURIO: Objection to form.</p> <p>8 A. Do you want me to give you a subjective answer?</p> <p>9 Q. Let me rephrase the question. Has Arthrex</p> <p>10 received feedback from surgeons on the handleability of</p> <p>11 Arthrex's FiberWire suture?</p> <p>12 A. Yes.</p> <p>13 Q. And what was the feedback that Arthrex received</p> <p>14 from surgeons on the handleability of Arthrex's FiberWire</p> <p>15 suture?</p> <p>16 A. That it's easy to utilize.</p> <p>17 Q. And what surgeons provided that feedback?</p> <p>18 A. I have heard Dr. Burkhardt say that.</p> <p>19 Q. Anyone else?</p> <p>20 A. Not directly to me, no.</p> <p>21 Q. Have any doctors provided negative feedback to</p> <p>22 Arthrex on the handleability of Arthrex's FiberWire</p> <p>23 suture?</p> <p>24 A. Yes.</p> <p>25 Q. How many doctors have provided negative feedback</p>
<p>31</p> <p>1 product manager or a surgeon who is familiar with the</p> <p>2 field of sutures and ask them to give us feedback on the</p> <p>3 handleability.</p> <p>4 Q. And what is handleability measured in?</p> <p>5 A. There are no units. It's subjective.</p> <p>6 Q. So what does "handleability" mean? What does the</p> <p>7 definition of "handleability" mean as Arthrex uses that as</p> <p>8 a test for its FiberWire sutures?</p> <p>9 A. What do I think it means?</p> <p>10 Q. What does Arthrex think it means?</p> <p>11 A. I think handleability as is it easy to move</p> <p>12 through the tissue or pass through the tissue? Is it easy</p> <p>13 to slide knots? Is it easy to tie knots?</p> <p>14 Q. Anything else?</p> <p>15 A. Is it easy to slide through the anchor eyelet?</p> <p>16 Q. Anything else?</p> <p>17 A. Not that I can think of.</p> <p>18 Q. Do materials contribute to the handleability of</p> <p>19 Arthrex's FiberWire sutures?</p> <p>20 MR. TAMBURIO: Objection to form.</p> <p>21 A. Yes.</p> <p>22 MR. TAMBURIO: Also, it's outside the scope.</p> <p>23 Q. What materials contribute to the handleability of</p> <p>24 Arthrex's FiberWire sutures?</p> <p>25 A. All materials used.</p>	<p>33</p> <p>1 to Arthrex on the handleability of Arthrex's FiberWire</p> <p>2 suture?</p> <p>3 A. I know of only one account.</p> <p>4 Q. And who was that?</p> <p>5 A. I believe, again, it might have been Dr.</p> <p>6 Burkhardt.</p> <p>7 Q. And what negative feedback did Dr. Burkhardt</p> <p>8 provide to Arthrex on the handleability of Arthrex's</p> <p>9 FiberWire sutures?</p> <p>10 A. That the nylon was too repetitious in the</p> <p>11 TigerWire.</p> <p>12 Q. What does that mean?</p> <p>13 A. It means there were too many wraps.</p> <p>14 Q. And that affected the handleability of the</p> <p>15 suture?</p> <p>16 A. That affected the feel.</p> <p>17 Q. Is the feel like handleability, or is that</p> <p>18 another word for handleability -- feel?</p> <p>19 A. Feel would fall under handleability; how does it</p> <p>20 feel in your hands.</p> <p>21 Q. All right. So that's one criteria used for the</p> <p>22 handleability?</p> <p>23 A. Right.</p> <p>24 Q. As well as passing the suture through tissue or</p> <p>25 any other things you described?</p>

BROOKSTEIN DECLARATION EXHIBIT 18

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC.,
a Massachusetts corporation,

Plaintiff,

v.

Case No: CA-0412457-PBS

ARTHREX, INC, a
Delaware corporation,

Defendant.

VIDEOTAPE DEPOSITION OF ANN WATERHOUSE

TAKEN: Pursuant to Notice by
Counsel for the Plaintiff

PLACE: Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34109

DATE: Wednesday, August 24, 2005

TIME: Began: 8:55 a.m.
Ended: 1:00 p.m.

BEFORE: TRACIE L. MOUNTAIN-THOMPSON
Court Reporter
Notary Public
State of Florida at Large

COPY

Page 46

1 Q What does that mean?

2 A In the first paragraph, under suture
3 weight, which is coating, it says, "Pearsalls makes the
4 following statement about the NuSil coating applied to
5 both our Arthrex FiberWIRE and other competitive
6 product."

7 So they're demonstrating their processing of
8 that coating by the statement that follows.

9 Q That statement is from NuSil, not from Arthrex?

10 A No. That's from Pearsalls.

11 Q All right. But just to be clear, the coating
12 on the FiberWIRE product is MED-2174, right?

13 A Correct.

14 Q Okay. And in that last paragraph on page
15 2104, the second sentence says, "As noted (above) we
16 cannot measure the amount of coating so the product is
17 accepted by our customers on the basis of an agreed
18 detailed coating process which includes mixing the NuSil
19 to a certain viscosity and the speeds, temperatures, and
20 other parameters for the coating process. For each
21 coating batch all these details are recorded in the batch
22 documentation available to you and other customers."

23 Do you see that?

24 A Yes.

25 Q What does that mean?

Page 48

1 A Correct.

2 Q "We," Pearsalls, "cannot measure the amount of
3 coating so the product is accepted by our customers on
4 the basis of an agreed detailed coating process which
5 includes mixing the NuSil to a certain viscosity and the
6 speeds, temperatures and other parameters for the coating
7 process."

8 A Correct.

9 Q So does Arthrex accept batches of FiberWIRE
10 based on the coating?

11 MR. SABER: Objection. Vague. Confusing
12 question.

13 BY MR. FALKE:

14 Q All right. Was Pearsalls representing to
15 Arthrex that it cannot measure the amount of coating on
16 the FiberWIRE product when Arthrex submitted this
17 statement to the FDA in Exhibit 81?

18 A Can you repeat the question.

19 Q Sure.

20 Was Pearsalls representing to Arthrex that
21 Pearsalls cannot measure the amount of coating on the
22 FiberWIRE product when Arthrex submitted Exhibit 81 to
23 the FDA?

24 A Yes, as a percentage.

25 Q As a percentage of what?

Page 47

1 A That means that that's the processing that
2 they -- they put onto our product and it's describing
3 that they do it to a certain viscosity. They do it at a
4 certain speed and temperature. And they have other
5 parameters for the coating process. So that coating
6 process is an agreed upon process by their buyers.
7 basically, so that's what it is. That's how it's
8 actually done.

9 Q Does Arthrex and Pearsalls have an agreed -- an
10 agreed detailed coating process?

11 A Not that I know of.

12 Q So how does Arthrex know how the FiberWIRE
13 coating is applied to its FiberWIRE product?

14 A Specifically, they could ask for that batch
15 record for each lot that is produced, but in
16 general, they know the coating process because of the
17 temperature and speed, and the parameters that Pearsalls
18 uses coats that in an even manner, so it's an assumption.

19 Q Is it true that Pearsalls cannot measure the
20 amount of coating on the FiberWIRE product?

21 MR. SABER: Objection. Inconsistent with the
22 testimony.

23 BY MR. FALKE:

24 Q I'm just looking. It says -- on page 2104 it
25 says, "We," and I assume that's Pearsalls; is that right?

Page 49

1 A The total weight of the suture.

2 Q Has Arthrex submitted any document to the FDA
3 in any submission which details the coating process
4 Pearsalls uses to coat any FiberWIRE suture?

5 A No.

6 Q Why not?

7 A Because we used the statement as a reference
8 point so that we didn't have to submit anything about the
9 coating process. We described it instead.

10 Q You say "the statement," which statement is
11 that?

12 A On 2104, the statement that Pearsalls makes.

13 Q Okay. And then it says, in the last sentence
14 on page 2104, "For each coating batch all these details
15 are recorded in the batch documentation available to you
16 and other customers."

17 Do you see that?

18 A Yes.

19 Q Is the reference to "you" in that sentence,
20 does that refer to Arthrex?

21 A Correct.

22 Q Does Arthrex have any documents which reflect
23 the details of the coating process for the batches of
24 FiberWIRE it receives?

25 A Not that I know of.

13 (Pages 46 to 49)

1 Q Does Arthrex have the ability to obtain those
2 documents?

3 A Yes.

4 Q So Pearsall's can determine the percentage --
5 cannot determine the percentage of coating to the total
6 weight of the suture; is that right?

7 A Correct.

8 MR. SABER: Objection. Vague.

9 BY MR. FALKE:

10 Q I'm sorry, what was your answer?

11 A Correct.

12 Q And the reason they can't do that is because
13 they can't measure the amount of coating on it;
14 therefore, they can't measure the percentage of the
15 amount of coating to the total weight, right?

16 A Correct.

17 Q I'm going to reask that question because the
18 record is slightly unclear. So Pearsall's cannot
19 determine the percentage of coating to the total weight
20 of the suture; is that right?

21 MR. SABER: Could you read that question back,
22 please.

23 (The court reporter read back the requested
24 portion of testimony.)

25 MR. SABER: Objection. Vague. Asked and

1 answered.

2 BY MR. FALKE:

3 Q You can answer.

4 A Correct.

5 Q Okay. If you could turn to page 2130, please,
6 in Exhibit 81.

7 I'm sorry, are you there?

8 A Uh-huh.

9 Q If you look at the last paragraph on that page,
10 2130, and in particular, the last sentence, it says --
11 excuse me, let me step back. The second to the last
12 paragraph on page 2130, it says, in the last sentence of
13 that paragraph, "The dyed polyester suture (D & C Blue
14 No. 6) and di-peroxide silicone oil (coating) are
15 pharmacologically inactive."

16 Do you see that?

17 A Yes, I do.

18 Q Does the di-peroxide silicone oil (coating)
19 refer to the MED-2174 that's applied to the FiberWIRE
20 product?

21 A Yes, it does.

22 Q And what does that mean "pharmacologically
23 inactive"?

24 A Pharmacologically inactive means that it does
25 not cause any reaction when tested.

1 Q What do you mean by "when tested"?

2 A We test according to 10993, which is cited in
3 that paragraph.

4 Q Uh-huh.

5 A There are certain tests that you have to
6 perform according to that based on the use of your
7 product. When they test that, as an example -- and
8 you've got both of the tests -- they test whether there
9 is a reaction or -- a negative reaction or an adverse
10 reaction as opposed to nothing happening.

11 Q Right.

12 A If it -- if there is nothing happening, they
13 consider that pharmacologically inactive.

14 Q Has Arthrex made any representation to the FDA
15 in any submission as to whether MED-2174 is absorbable in
16 the body?

17 A No.

18 Q Do you know if MED-2174 is absorbable in the
19 body?

20 A No.

21 Q No, you don't know?

22 A I don't know.

23 Q I think I asked this but I'm going to ask it
24 again. And Exhibit 81 was submitted to the FDA by
25 Arthrex, right?

1 A Yes, it was.

2 (Exhibit 82 was marked for identification.)

3 BY MR. FALKE:

4 Q Let me hand you Exhibit 82, which is a document
5 with Bates numbers ARM001882 through 1884. Have you seen
6 this document before?

7 A Yes, I have.

8 Q And what is Exhibit 82?

9 A This is the substantial equivalence letter for
10 K010673.

11 Q And that reference, that K number, 010673,
12 reverts to Exhibit 78, right?

13 A Correct.

14 Q And what is the purpose of this substantial
15 equivalence letter, Exhibit 82?

16 A It's the FDA's way of granting you permission
17 for sale of a product.

18 Q Okay. So through Exhibit 82 the FDA was
19 granting Arthrex the permission to sell Arthrex
20 FiberWIRE; is that right?

21 A Correct.

22 Q And Exhibit 82 is dated May 14th, 2001; is that
23 right?

24 A Correct.

25 Q Did Arthrex sell FiberWIRE prior to May 14th.

BROOKSTEIN DECLARATION EXHIBIT 19



April 26, 2001.

Food and Drug Administration
Center for Devices and Radiological Health
Attn: Mr. David Krause
Department of Health and Human Services, Public Health Service
Division of General & Restorative Devices
9200 Corporate Boulevard
Rockville, Maryland 20850

**RE: Amendment to Original Pre-Market Submission 510(k) #K010673,
Arthrex FiberWIRE™**

On February 28, 2001 the Arthrex FiberWIRE™ was submitted to the FDA. Per a conversation between Ann Waterhouse (Arthrex) and David Krause (FDA) on April 16, 2001, the following is being sent as amendment information. Specifically included are percentages for content, labeling amendments, and research data for accessory equipment.

Arthrex has submitted in duplicate the requested information and respectfully asks that these be accorded the same confidentiality as the original submission, K010673. We request that the Food and Drug Administration keep confidential all information outside of the 510(k) summary and indications for use.

Should the following information be in any way deficient, please let us know. We will be happy to provide you with any missing details or information. Should you have further questions concerning the amendment we have submitted, please contact either Vernon Brown or Ann Waterhouse at (941) 643-5553. Thank you.

Sincerely,

Ann Waterhouse
Regulatory Affairs Specialist

CONFIDENTIAL - NON-PATENT
PROSECUTION COUNSEL
ONLY

ARM 002103

1. In many places in the document the suture is described as being composed of polyester and ultrahigh molecular weight polyethylene (UHMWPE). Please describe the polyester and indicate what percentage of the suture weight is UHMWPE. Also, what percentage of the weight of the suture is the dye and what percentage of the weight of the suture is the coating?

Description of the polyester:

The Polyester used by Pearsalls to produce Arthrex FiberWIRE™ is created from high tenacity filaments of Polyethylene Terephthalate. Specifically, this is type 712 polyester that is manufactured by KoSa GmbH & Co KG.

% of the suture weight which is Ultra high molecular weight polyethylene:

Broken into percentage, the Polyester is 38.09% of the suture input and the Polyethylene (UHMW) is 61.91%.

Suture weight which is dye:

In using an accepted dye, D&C Blue No. 6, neither Pearsalls nor Arthrex measured the percentage of weight which the suture gained by the dye process. Pearsalls certifies that the process with which they dye the polyester conforms with the 2.0 Cupric Sulfate listed in the USP Matching Solutions table on page 1585 of USP 24. Also, Pearsalls certifies to all of its customers that the D&C Blue No. 6 is a FDA approved dye.

Suture weight which is coating:

Pearsalls makes the following statement about the NuSil coating applied to both our Arthrex FiberWIRE™ and other competitor product:

"The coating is a silicone rubber known as NuSil 2045. It is identical to the coating we apply for Davis & Geck silk suture, and is also used to coat "Ticron" polyester suture. As noted (above) we cannot measure the amount of coating so the product is accepted by our customers on the basis of an agreed detailed coating process which includes mixing the NuSil to a certain viscosity and the speeds, temperatures, and other parameters for the coating process. For each coating batch all these details are recorded in the batch documentation available to you and other customers."

CONFIDENTIAL - NON-PATENT
PROSECUTION COUNSEL
ONLY

000001

ARM 002104

2. You describe your suture as having a silicone elastomer coating. Please identify a legally marketed suture predicate that is coated with silicone.

The predicate devices with Nu-Sil silicone derivative or equivalent, used to coat silk and polyester suture are listed below. The 510 (k) summaries or statements for these predicate products are contained in the following pages:

K930586	Dermalon, Surgilon, Ophthalon, & Ophthalmic Suture
K930590	Silk Sutures
K961925	Polyester Non-Absorbable Surgical Suture
K990088	Synthofil Non-Absorbable PET Surgical Suture
K001172	Polyester Non-Absorbable Surgical Suture
K003590	Grams Polyester Non-Absorbable Suture

CONFIDENTIAL - NON-PATENT
PROSECUTION COUNSEL
ONLY

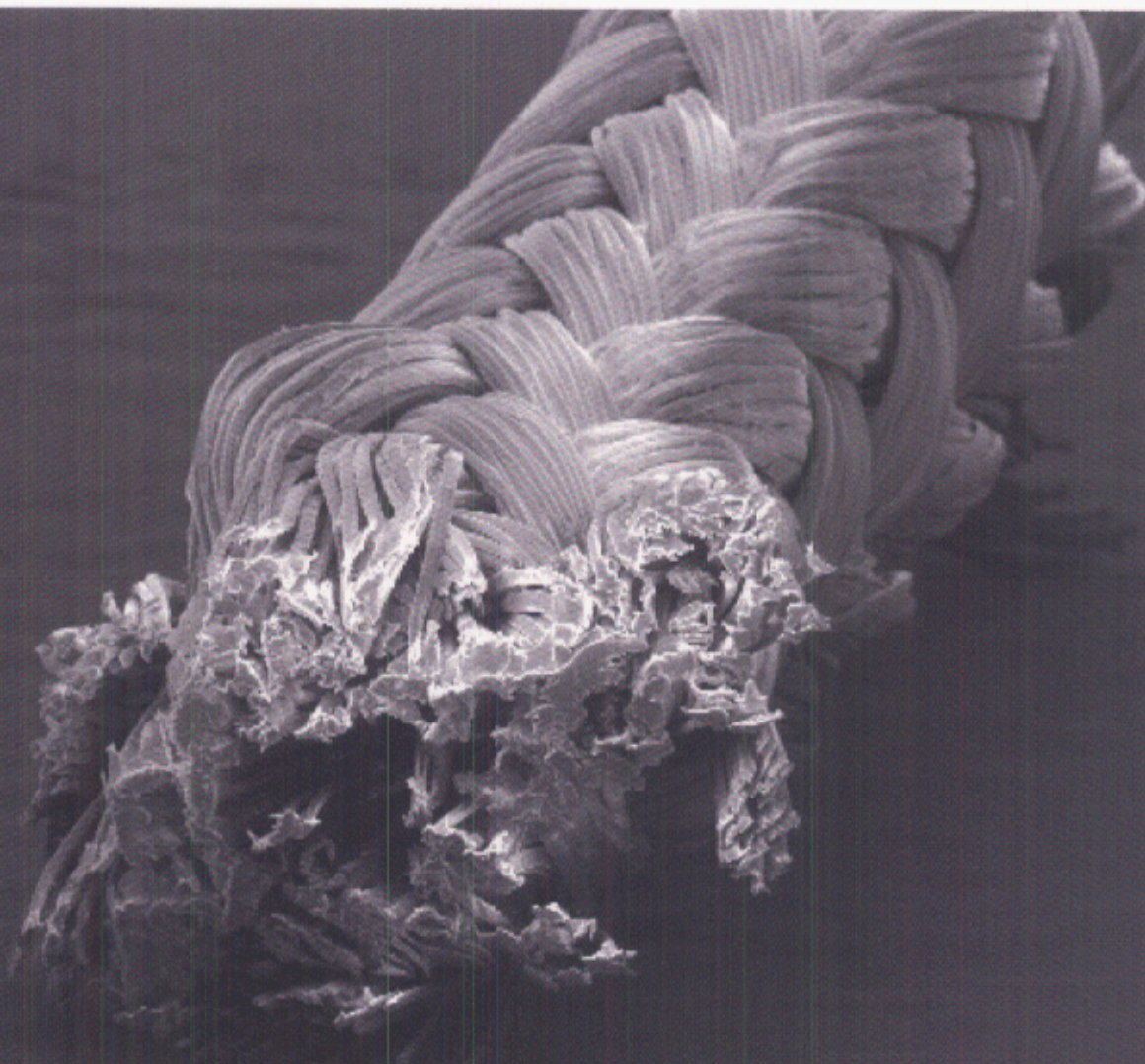
ARM 002105

000002

BROOKSTEIN DECLARATION EXHIBIT 20



BROOKSTEIN DECLARATION EXHIBIT 21



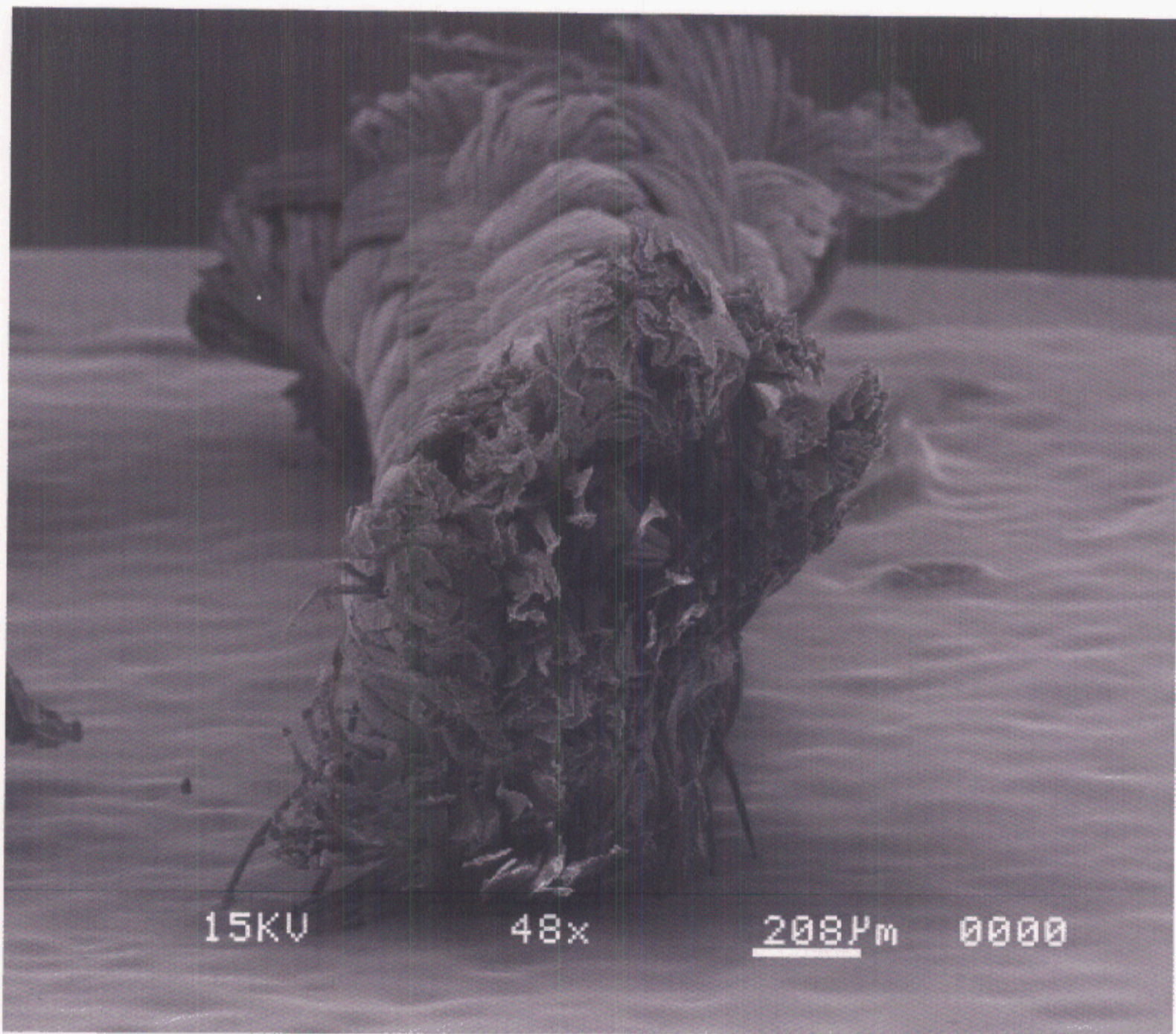
15KV

48x

208µm

0000

BROOKSTEIN DECLARATION EXHIBIT 22



BROOKSTEIN DECLARATION EXHIBIT 23

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

-O-

DEPUY MITEK, INC., a :
Massachusetts Corporation, : Civil Action No.
: 04-12457 PBS
Plaintiff, :

-vs-

:
ARTHREX, INC., a Delaware :
Corporation, and PEARSALLS : EXPERT DEPOSITION OF:
LTD., a Private Limited : ROBERT T. BURKS, M.D.
Company of the United :
Kingdom, :

Defendants.

-O-

Location: Marriott University Hotel
Salt Lake City, Utah

Date: June 7, 2006
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

-O-

<p>1 APPEARANCES</p> <p>2 For the Plaintiff:</p> <p>3 ERICH M. FALKE and</p> <p>4 MICHAEL J. BONELLA</p> <p>5 WOODCOCK WASHBURN, LLP</p> <p>6 One Liberty Place - 46th Floor</p> <p>7 Philadelphia, PA 19103</p> <p>8 (215)564-8987</p> <p>9 (215)568-3439 (fax)</p> <p>10 Efalke@woodcock.com</p> <p>11 For the Defendant:</p> <p>12 SALVATORE P. TAMBURIO</p> <p>13 DICKSTEIN SHAPIRO MORIN OSHINSKY</p> <p>14 2101 L Street NW</p> <p>15 Washington, DC 20037-1526</p> <p>16 (202)822-5164</p> <p>17 (202)887-0689 (fax)</p> <p>18 TamburoS@dsmo.com</p> <p>19 -O-</p> <p>20 INDEX</p> <table border="1"> <thead> <tr> <th>Witness</th> <th>Page</th> </tr> </thead> <tbody> <tr> <td>ROBERT T. BURKS, M.D.</td> <td></td> </tr> <tr> <td>Examination by Mr. Falke</td> <td>4</td> </tr> <tr> <td>Examination by Mr. Tamburo</td> <td>99</td> </tr> <tr> <td>-O-</td> <td></td> </tr> </tbody> </table>	Witness	Page	ROBERT T. BURKS, M.D.		Examination by Mr. Falke	4	Examination by Mr. Tamburo	99	-O-		<p>1 June 7, 2006 3:05 p.m.</p> <p>2 PROCEEDINGS</p> <p>3 (Discussion off the record.)</p> <p>4 THE VIDEOGRAPHER: We are on record at</p> <p>5 3:05. This is the videotape deposition of Dr. Robert</p> <p>6 T. Burks taken on June 7, 2006 in the matter of DePuy</p> <p>7 Mitek, Incorporated, a Massachusetts corporation.</p> <p>8 versus Arthrex, Incorporated, a Delaware corporation.</p> <p>9 The case number is 04-12457 PBS in the</p> <p>10 United States District Court for the District of</p> <p>11 Massachusetts.</p> <p>12 My name is Donna Polton. I'm a licensed</p> <p>13 videographer. The court reporter is Denise Kirk. We</p> <p>14 represent the firm of Veritext Corporate Services.</p> <p>15 Counsel will now state their appearances</p> <p>16 for the record and the witness will be sworn in.</p> <p>17 MR. FALKE: Erich Falke and Michael</p> <p>18 Bonella from Woodcock Washburn representing plaintiff</p> <p>19 DePuy Mitek.</p> <p>20 MR. TAMBURIO: Salvatore Tamburo</p> <p>21 representing Arthrex Inc.</p> <p>22 ROBERT T. BURKS, M.D.</p> <p>23 Called as a witness herein, being</p> <p>24 First duly sworn was examined</p> <p>25 And testified as follows:</p>						
Witness	Page																
ROBERT T. BURKS, M.D.																	
Examination by Mr. Falke	4																
Examination by Mr. Tamburo	99																
-O-																	
<p>1 EXHIBITS</p> <p>2 (All Exhibits premarked by Mr. Falke)</p> <table border="1"> <thead> <tr> <th>Number</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>231</td> <td>Subpoena in a Civil Case</td> </tr> <tr> <td>232</td> <td>Expert Report of Robert Burks, M.D.</td> </tr> <tr> <td>233</td> <td>Curriculum Vitae</td> </tr> <tr> <td>234</td> <td>Chart of sutures</td> </tr> <tr> <td>235</td> <td>Sutures retained by Mr. Falke</td> </tr> <tr> <td>236</td> <td>Sutures retained by Mr. Falke</td> </tr> <tr> <td>237</td> <td>Sutures retained by Mr. Falke</td> </tr> </tbody> </table> <p>11 -O-</p>	Number	Description	231	Subpoena in a Civil Case	232	Expert Report of Robert Burks, M.D.	233	Curriculum Vitae	234	Chart of sutures	235	Sutures retained by Mr. Falke	236	Sutures retained by Mr. Falke	237	Sutures retained by Mr. Falke	<p>1 EXAMINATION</p> <p>2 BY MR. FALKE:</p> <p>3 Q. Good afternoon, Dr. Burks. How are you?</p> <p>4 A. Good.</p> <p>5 Q. Have you ever been deposed before. Dr.</p> <p>6 Burks?</p> <p>7 A. Yes.</p> <p>8 Q. On how many occasions have you been</p> <p>9 deposed?</p> <p>10 A. Several. I don't know a number.</p> <p>11 Q. More than five?</p> <p>12 A. Yeah.</p> <p>13 Q. Less than ten?</p> <p>14 A. Reasonable.</p> <p>15 Q. I'm just going to go over a few of the</p> <p>16 ground rules to make sure we're on the same page.</p> <p>17 Periodically we'll be taking breaks, roughly once an</p> <p>18 hour. But if there's any time you feel you need to</p> <p>19 take a break, let us know and we'll accommodate you as</p> <p>20 soon as we can.</p> <p>21 Do you understand you've taken an oath to</p> <p>22 tell the truth today?</p> <p>23 A. Yes.</p> <p>24 Q. And that leads me to the next one. All</p> <p>25 answers, could you please make them verbal so that the</p>
Number	Description																
231	Subpoena in a Civil Case																
232	Expert Report of Robert Burks, M.D.																
233	Curriculum Vitae																
234	Chart of sutures																
235	Sutures retained by Mr. Falke																
236	Sutures retained by Mr. Falke																
237	Sutures retained by Mr. Falke																

2 (Pages 2 to 5)

<p>1 court reporter can transcribe them as opposed to 2 shaking your head or nodding your head: do you 3 understand that? 4 A. Yes. 5 Q. Also, if you'll allow me to finish the 6 question before you answer, it will make for a better 7 transcript. Even though you may even be able to 8 anticipate the end of my question by what I say in the 9 beginning, if you'd allow me to finish and then answer 10 it will allow the reporter to make a clear transcript; 11 do you understand that? 12 A. I do. 13 Q. Also, if I ask you a question and you 14 don't understand, I'll ask that you tell me you don't 15 understand the question. Otherwise, I'll assume that 16 you did understand the question; is that fair? 17 A. Fair. 18 Q. Are you being represented today by 19 counsel? 20 A. Yes. 21 Q. Who is your counsel? 22 A. Sal Tamburo. 23 Q. Do you know when Sal or the law firm 24 Dickstein Shapiro Morin & Oshinsky began representing 25 you for purposes of this case?</p>	<p>6 1 A. Yes. 2 Q. What is Exhibit Number 231? 3 A. A subpoena for me. 4 Q. Did you understand that be Exhibit 231 was 5 a subpoena on you for certain documents and things 6 listed in schedule A of Exhibit 231? 7 A. Yes. 8 Q. Today are you producing any documents or 9 things in response to the subpoena. Exhibit 231? 10 A. No. 11 Q. If you could turn to page two of Exhibit 12 Number 231, please. Do you see request number one for 13 documents there, being all communications between any 14 of Arthrex, you, Dr. Mukherjee and Dickstein Shapiro 15 Morin & Oshinsky concerning the lawsuit commenced by 16 the plaintiff attached as Exhibit 1? 17 A. Yes. 18 Q. Did you perform any search that might be 19 responsive to request number one in Exhibit Number 20 231? 21 A. Yes. 22 Q. Did you find any? 23 A. No. 24 Q. Request number two in Exhibit 231 is all 25 documents concerning this lawsuit, including, but not</p>
<p>7 1 A. In February. 2 Q. Is that when Arthrex or Dickstein 3 contacted you with respect to your role in this case? 4 A. Yes. 5 Q. Are you being compensated for the time you 6 spend on this lawsuit? 7 A. Yes. 8 Q. How are you being compensated? 9 A. How much? 10 Q. Yes. 11 A. \$400 an hour. 12 Q. Was that a negotiated fee or was that your 13 standard fee for doing expert consulting? 14 A. I don't really have a standard fee, so I 15 guess you could call it negotiated. 16 Q. Other than money, is there any other 17 compensation you are receiving for work on this case? 18 A. No. 19 Q. Were you given any dollar amount that you 20 should not exceed in performing work for Arthrex in 21 this case? 22 A. No. 23 Q. I'm going to hand you DePuy Mitek Exhibit 24 231 and ask you if you recognize this document, 25 Exhibit 231?</p>	<p>9 1 limited -- well, hold on. Strike that. 2 Did you perform a reasonable search for 3 documents in response to request number two in 4 Schedule A of Exhibit 231? 5 A. I guess I don't see the difference. There 6 aren't any documents that I'm aware of in the lawsuit. 7 Q. Under things to be produced on page two of 8 Exhibit Number 231, request number one is all tested 9 and untested samples referred to in Expert Report of 10 Robert T. Burks, MD dated March 24, 2006, including, 11 but not limited to suture A and suture B. Do you see 12 that? 13 A. I do. 14 Q. Did you perform a search for things 15 responsive to request number one? 16 A. No. 17 Q. You did not? 18 A. I knew it didn't exist. 19 Q. You knew what didn't exist? 20 A. The suture. 21 Q. You mean the tested and untested samples? 22 A. The pieces that I had I had disposed of 23 when I was done. I knew there wasn't anything to look 24 for. 25 Q. Under request number two on things to be</p>

<p>10</p> <p>1 produced on page two of Exhibit 231 is all equipment 2 used to test the samples as described in paragraphs 3 nine through 13 of Expert Report of Robert T. Burks, 4 MD dated March 24, 2006, including, but not limited to 5 the equipment that was used to cut and wet the samples 6 and to conduct the tactile feel analysis and knot 7 tie-down analysis; do you see that? 8 A. I do. 9 Q. Did you perform a search for the materials 10 requested in request number 2? 11 A. No. 12 Q. Why not? 13 A. The equipment that was used was a pair of 14 scissors just to cut it, something from home, I felt 15 like it didn't have relevance. 16 Q. What about the solution that was used to 17 wet these tested samples? 18 A. I used tap water. 19 Q. Did you use anything else in performing 20 the tests described in paragraphs nine through 13 of 21 your expert report other than tap water and scissors 22 and the sutures? 23 MR. TAMBURRO: It might help if the witness 24 had his report in front of him to refer to. 25 A. The things used, like a pair of gloves,</p>	<p>12</p> <p>1 Q. What about medical school? 2 A. '78. 3 Q. Then, after medical school, where did you 4 go? 5 A. To residency training. 6 Q. When did you finish your residency 7 training? 8 A. '83. 9 Q. Where was your residency training? 10 A. University of California San Diego. 11 Q. Did you have a specialty there? 12 A. Yes. Well, there's no specialty in 13 training per se, but I did do a fellowship during that 14 time with Dale Daniel at Kaiser Permanente. 15 Q. What was that fellowship in? 16 A. Knee and sports medicine. 17 Q. When did you finish your fellowship in 18 knee and sports medicine? 19 A. '83. 20 Q. Other than those programs or degrees you 21 mentioned, are there any other -- is there any other 22 formal education that you've gone through? 23 A. No. 24 Q. Once you completed your fellowship in knee 25 and sports medicine in 1983, what did you do?</p>
<p>11</p> <p>1 are disposed of after and they're just a generic set. 2 There wasn't anything used that would be unique that I 3 felt would be worthwhile to produce. 4 Q. So you used gloves when you performed the 5 tactile feel analysis and knot tie-down analysis? 6 A. I did both. I used and didn't use gloves. 7 Q. Is there any reason why you decided not to 8 bring gloves today? 9 A. No. 10 Q. Did your counsel advise you to bring 11 gloves? 12 A. No. 13 Q. Did you go over -- did you have a chance 14 to go over Exhibit 231 with your counsel before coming 15 to today's deposition? 16 A. Yes, we looked at it. 17 Q. Dr. Burks, could you please describe your 18 formal education post-high school for me, please. 19 A. I did medical school at St. Louis 20 university. I guess after high school I did college 21 at Southern Methodist University, medical school at 22 St. Louis university, orthopedic training at 23 University of California San Diego. 24 Q. When did you graduate from undergrad? 25 A. Undergrad college was '74.</p>	<p>13</p> <p>1 A. I went into private practice in St. Louis, 2 Missouri. 3 Q. What was the focus of your private 4 practice in St. Louis? 5 A. Sports medicine, general orthopedics. 6 Q. Did you focus on any particular parts of 7 the body within sports medicine and general 8 orthopedics? 9 A. Knee and shoulder were the big focus. 10 Q. And when did you leave private practice in 11 St. Louis? 12 A. I was there three years; I believe it was 13 '86. 14 Q. Then what did you do in 1986? 15 A. I went to Wayne State University in 16 Detroit. 17 Q. What did you do at Wayne State? 18 A. I was on the academic staff there and was 19 the head of sports medicine. 20 Q. Your time spent at Wayne State, was that 21 strictly in an academic environment or did that also 22 include a clinical practice? 23 A. Yes. I mean, it was a clinical practice, 24 but it was as a full-time faculty member. 25 Q. Can you explain how that works, your role</p>

<p>14</p> <p>1 at Wayne State, how it was spent between full-time 2 faculty member and participating in a clinical 3 practice? 4 A. Well, there's really no distinction. I 5 mean, my job was to take care of patients and people. 6 And so the education was for residents and that's what 7 they were training to do was take care of people. 8 So there really wasn't a distinction 9 between a clinical practice and what you are doing 10 academically as far as your work goes. 11 Q. So did you teach in a classroom setting? 12 A. No. 13 Q. So I think I understand. What type of 14 medicine did you practice at Wayne State as a 15 full-time faculty member and in a clinical practice? 16 A. It was orthopedic surgery with an emphasis 17 in sports medicine. 18 Q. Again, did you focus on the knee and 19 shoulder areas? 20 A. Yes. 21 Q. When you were at Wayne State what were the 22 -- generally what were the procedures that you would 23 perform for shoulder surgeries? 24 A. Perform shoulder instability operations, 25 rotator cuff operations, things that we do for what we</p>	<p>16</p> <p>1 Q. In 1988 after leaving Wayne State, what 2 did you do? 3 A. I came here to the University of Utah. 4 Q. What position did you enter the University 5 of Utah in 1988? 6 A. I was an assistant professor in orthopedic 7 surgery. And we didn't really have a true division, 8 but I was part of the sports medicine team. 9 Q. Can you generally describe your duties as 10 an assistant professor in the orthopedic surgery 11 department at the University of Utah? 12 A. Duties were to take care of standard 13 patients that we would see, to instruct residents in 14 clinical evaluation of patients and surgical treatment 15 of patients, to be involved in some areas of research 16 and produce academically, and were involved with 17 taking care of the athletic teams. 18 Q. While at the University of Utah, I take it 19 from 1988 to the present you've remained at the 20 University of Utah? 21 A. Yes. 22 Q. From 1988 to the present, do you perform 23 any classroom teaching? 24 A. Minimally. Occasionally it comes up, but 25 not very much.</p>
<p>15</p> <p>1 call impingement, shoulder pain procedures, procedures 2 that revolve around the clavicle. 3 Q. Anything else you can think of? 4 A. I mean, it's a pretty wide area, but those 5 are the main things. 6 Q. What about when you were at Wayne State, 7 what were the procedures that you would perform for 8 knee surgeries? 9 A. Ligament reconstructions, operations for 10 instability of the knee cap, cartilage procedures, 11 meniscus procedures. 12 Q. When you were at Wayne State, did you 13 perform any ankle surgeries? 14 A. Sure. 15 Q. What ankle surgeries? What procedures 16 would you perform doing ankle surgeries? 17 A. The main procedures revolved around 18 arthroscopy, and then I would do some procedures that 19 revolved around loose ankle joints where people have 20 chronic ankle sprains and tightening those up. 21 Q. Then, I take it, at some point you left 22 Wayne State? 23 A. Correct. 24 Q. What year was that? 25 A. '88.</p>	<p>17</p> <p>1 Q. What classes would you teach when it comes 2 up? 3 A. It's usually just an isolated lecture, not 4 like a class series. So it would be lectures to the 5 residents or to medical students on a specific topic, 6 sometimes to physical therapy students. 7 Q. Since 1988, how have your duties and 8 responsibilities at the University of Utah changed? 9 A. I don't think they've changed much. 10 Q. Okay. At some point you did become head 11 of the sports medicine division, though, right? 12 A. Correct. 13 Q. Do you know when that happened? 14 A. I'd be guessing a little. I'm not sure of 15 the exact year. 16 Q. How about 1992, does that sound familiar? 17 A. That's probably close. 18 Q. Dr. Burks, I'm going to hand you Exhibit 19 Number 233. This is a printout of a web page from the 20 University of Utah. If you could just please look at 21 that. 22 MR. TAMBURRO: Do you have another copy? 23 Q. No. Just let me know if that's generally 24 accurate. 25 A. Yes.</p>

<p style="text-align: right;">18</p> <p>1 Q. Dr. Burks, can you describe for me your 2 relationship with Arthrex, Inc.?</p> <p>3 MR. TAMBURO: Objection, vague.</p> <p>4 A. I am a consumer. Over the years I have 5 been an advisor for different products. That's it.</p> <p>6 Q. You say you are a consumer of Arthrex 7 products. What Arthrex products do you use?</p> <p>8 A. Well, we use things like drill guides, use 9 suture anchors and sutures, drill bits. That's it.</p> <p>10 Q. Do you use any Arthrex knee fixation 11 devices?</p> <p>12 A. I have used Arthrex knee fixation devices 13 but don't currently use any.</p> <p>14 Q. What did you use?</p> <p>15 A. They have an interference screw that is 16 metal and one that is absorbable that I used to use 17 that I don't use now.</p> <p>18 Q. Earlier you said things like we used 19 things like drill guides, suture anchors, and sutures, 20 drill bits. Who were you referring to when you said 21 "we"?</p> <p>22 A. I guess it was the generic "we" of the 23 sports medicine service.</p> <p>24 Q. Do you personally use those Arthrex 25 products?</p>	<p style="text-align: right;">20</p> <p>1 Q. Other than royalties and other than money 2 for your work you've performed in this lawsuit, do you 3 receive any other money from Arthrex?</p> <p>4 A. No.</p> <p>5 Q. How many different pieces of Arthrex 6 equipment to you receive royalties on?</p> <p>7 A. There is a knee ligament guide system that 8 has a few different pieces in it. So I can't give an 9 exact number. It's sort of a guide system with four 10 or five different pieces, parts of it.</p> <p>11 There is a screw that we use for 12 augmenting ligament fixation that I get some royalties 13 on along with those guides.</p> <p>14 Q. Do you know what the trade name is for the 15 knee ligament guides that you receive royalties from 16 Arthrex on?</p> <p>17 A. It's kind of silly that I wouldn't be able 18 to give you that. It's for posterior cruciate 19 ligament reconstruction.</p> <p>20 Q. And do you know what the trade name is on 21 the screw that you receive royalties from Arthrex on?</p> <p>22 A. I don't.</p> <p>23 Q. For what area of the body is this screw 24 used on?</p> <p>25 A. It could be used anywhere, but I think the</p>
<p style="text-align: right;">19</p> <p>1 A. Oh, yes.</p> <p>2 Q. Do you have any consulting agreements with 3 Arthrex?</p> <p>4 A. To be honest, I'm not sure of the direct 5 answer to give you on that. I have a couple of pieces 6 of equipment that I have worked with them on in 7 developing, so that might be considered a consulting 8 agreement.</p> <p>9 I'm not a consultant, just a generic like 10 on a board of advisors or something like that.</p> <p>11 Q. I don't understand when you say "I have a 12 couple of pieces of equipment I worked with them on in 13 developing so that might be considered a consulting 14 agreement", could you explain that?</p> <p>15 A. Well, I went to them to develop a guide 16 for a knee ligament reconstruction. They liked the 17 idea. They made the guide. They have the guide as one 18 of the products that they sell, and then I get some 19 royalty from their sales.</p> <p>20 Q. Okay. So other than services you performed 21 for this case, have you received money from Arthrex 22 for other services such as, for example, this work you 23 did with the guide?</p> <p>24 A. I think I just said I get royalties for 25 that.</p>	<p style="text-align: right;">21</p> <p>1 large majority would be at the knee.</p> <p>2 Q. Are you the named inventor on any patents?</p> <p>3 A. No.</p> <p>4 Q. The screw that you developed with Arthrex, 5 is that used for the ACL or PCL?</p> <p>6 A. Can be either.</p> <p>7 Q. Is that an interference screw?</p> <p>8 A. No. It's a screw we typically refer to as 9 a post. And what that means is that suture from a 10 ligament or tendon gets tied around this to help hold 11 it while it's healing in.</p> <p>12 Q. You also said, in describing your 13 relationship with Arthrex, you used the word 14 "advisor". We've just been talking about you 15 developing certain equipment. Is that what you meant 16 by advisor?</p> <p>17 A. Yes.</p> <p>18 Q. Do you advise Arthrex in any other way 19 other than what we've just talked about with respect 20 to developing equipment?</p> <p>21 A. No.</p> <p>22 Q. Do you know Dr. Paul Fenton from Toledo, 23 Ohio?</p> <p>24 A. I don't.</p> <p>25 Q. What about Dr. Marlow Goebel?</p>

6 (Pages 18 to 21)

<p>22</p> <p>1 A. I do.</p> <p>2 Q. How do you know Dr. Goebel?</p> <p>3 A. Dr. Goebel practices in Logan, and is an</p> <p>4 adjunct faculty here at the University. So I've known</p> <p>5 him pretty much since I came here in '88.</p> <p>6 Q. Does Dr. Goebel have a reputation in the</p> <p>7 field?</p> <p>8 A. Sure.</p> <p>9 Q. Do you know that reputation is?</p> <p>10 A. Well, I know my perception of his</p> <p>11 reputation. I think he is a very inventive,</p> <p>12 unique-thinking orthopedic surgeon who has focused his</p> <p>13 career on knee surgery.</p> <p>14 Q. What about Dr. Richard Greenwald, not a</p> <p>15 medical doctor, but I believe he's a PhD?</p> <p>16 A. No.</p> <p>17 Q. Generally speaking, how much in royalties</p> <p>18 have you received from Arthrex for your work in</p> <p>19 developing the equipment that we've just talked about?</p> <p>20 A. I couldn't give you an exact number, but I</p> <p>21 would say the royalties in a given year probably</p> <p>22 fluctuate between seven and ten or \$11,000.</p> <p>23 Q. Have you ever been to Naples, Florida to</p> <p>24 visit Arthrex?</p> <p>25 A. Yes.</p>	<p>24</p> <p>1 Q. When you went to Arthrex, who paid for the</p> <p>2 visits?</p> <p>3 A. The meeting that was held was paid for by</p> <p>4 Arthrex. The other visit, I don't honestly remember</p> <p>5 how I got down there.</p> <p>6 Q. The first time you went to Arthrex, how</p> <p>7 many days did you stay down in Naples?</p> <p>8 A. I'm going to say two.</p> <p>9 Q. The second time?</p> <p>10 A. Two to two and-a-half.</p> <p>11 Q. Other than a consumer and advisor, how</p> <p>12 else would you describe your relationship with</p> <p>13 Arthrex?</p> <p>14 A. I've known the president of the company</p> <p>15 since near the beginning of the development of the</p> <p>16 company. So I've had interactions suggesting things</p> <p>17 that might be beneficial to look at or might improve</p> <p>18 patient care in certain circumstances. I've had that</p> <p>19 kind of relationship, I think.</p> <p>20 Q. Anything else?</p> <p>21 A. No.</p> <p>22 Q. How long have you been a consumer of</p> <p>23 Arthrex products?</p> <p>24 A. Well, from pretty much when they got</p> <p>25 rolling, which I don't remember exactly, I'm going to</p>
<p>23</p> <p>1 Q. On how many occasions have you gone to</p> <p>2 Naples to visit Arthrex?</p> <p>3 A. I believe twice.</p> <p>4 Q. What did you do when you went to Arthrex?</p> <p>5 A. One of the visits was a meeting which had</p> <p>6 orthopedic surgeons from the United States and Europe</p> <p>7 and some South America. And it was an academic</p> <p>8 meeting but, obviously, focused on Arthrex things.</p> <p>9 One time was just as they had opened their</p> <p>10 new manufacturing plants and facilities and it was to</p> <p>11 tour and visit.</p> <p>12 Q. When was the first time you were at</p> <p>13 Arthrex?</p> <p>14 A. I'd be guessing. I'm going to say maybe</p> <p>15 six years ago.</p> <p>16 Q. When was the second time you visited</p> <p>17 Arthrex?</p> <p>18 A. About two or three years ago.</p> <p>19 Q. How many years have you been receiving</p> <p>20 royalties from Arthrex on the knee ligament guide?</p> <p>21 A. I don't know for sure. I'm going to say</p> <p>22 five.</p> <p>23 Q. How many years have you been receiving</p> <p>24 royalties from Arthrex on the screw?</p> <p>25 A. Probably similar, maybe a year longer.</p>	<p>25</p> <p>1 say like 1990, but I don't know for sure.</p> <p>2 Q. Would you say you use more Arthrex</p> <p>3 products now than you did ten years ago?</p> <p>4 A. Certainly.</p> <p>5 Q. Why is that?</p> <p>6 A. They have more products now than they did</p> <p>7 ten years ago.</p> <p>8 Q. Any other reason?</p> <p>9 A. I like the products.</p> <p>10 Q. Anything else?</p> <p>11 A. No.</p> <p>12 Q. Dr. Burks, I'm going to hand you DePuy</p> <p>13 Mitek Exhibit 232. Could you identify Exhibit 232 for</p> <p>14 me please?</p> <p>15 A. 232 is my report to Sal Tamburo and my CV.</p> <p>16 Q. Did you write Exhibit Number 232?</p> <p>17 A. Well, I certainly had a hand in writing</p> <p>18 the CV. The other part of the report was written after</p> <p>19 conversation with Sal, by Sal.</p> <p>20 Q. So you talked to Sal and then Sal wrote</p> <p>21 the report and then did you sign it after it was</p> <p>22 written by Sal?</p> <p>23 A. Sal and I talked about the report, he</p> <p>24 wrote it, I reviewed it, had to make some changes here</p> <p>25 and there on background and what not, and then</p>

7 (Pages 22 to 25)

<p>26</p> <p>1 conversed with him about that and then signed the 2 final.</p> <p>3 Q. What changes did you make to the report 4 after Sal initially drafted it?</p> <p>5 A. I don't remember specifics, but I think 6 some of the background of when I did this or where I 7 was or something hadn't been finished, but I don't 8 remember the other specific changes.</p> <p>9 Q. Do you know if there are any drafts of 10 Exhibit 232?</p> <p>11 A. I don't have any.</p> <p>12 Q. Do you know if any exist?</p> <p>13 A. I don't know.</p> <p>14 Q. How was the initial draft prepared by Sal 15 sent to you?</p> <p>16 A. E-mail.</p> <p>17 Q. E-mail?</p> <p>18 A. Yes.</p> <p>19 Q. And then what did you do with the e-mail?</p> <p>20 A. Made a few changes and -- to be perfectly 21 honest, I can't remember if I made changes and sent 22 them back or got on the phone and said, hey, here's 23 where I would fill in this or change that. I don't 24 remember.</p> <p>25 Q. Do you remember physically or</p>	<p>28</p> <p>1 Q. Let me ask you the question again. Do you 2 remember when you signed the report. Exhibit 232?</p> <p>3 A. I will say March 24, 2006.</p> <p>4 Q. Do you remember what time of day you 5 signed Exhibit Number 232?</p> <p>6 A. No.</p> <p>7 Q. Do you remember where you were when you 8 signed Exhibit 232?</p> <p>9 A. I'm sure I was somewhere in my office.</p> <p>10 Q. Once you signed Exhibit 232, did you fax 11 it back to Sal?</p> <p>12 A. I don't remember.</p> <p>13 Q. Do you remember signing it in the morning?</p> <p>14 A. I don't remember.</p> <p>15 Q. Do you remember signing it in the 16 afternoon?</p> <p>17 A. No, I don't remember that.</p> <p>18 Q. Do you remember signing it at night?</p> <p>19 A. I don't. It wasn't a huge event in my life 20 so I...</p> <p>21 Q. So once it was signed, do you remember how 22 it was communicated back to Sal? Was it faxed or was 23 it overnighted?</p> <p>24 A. To be honest, I don't remember.</p> <p>25 Q. In the course of preparing the report, did</p>
<p>27</p> <p>1 electronically changing the word document and sending 2 it back to Sal?</p> <p>3 A. I don't remember doing that.</p> <p>4 Q. Do you remember printing it out?</p> <p>5 A. I don't.</p> <p>6 Q. Do you remember if you read it on the 7 screen or did you read it in hard copy form?</p> <p>8 A. I certainly read it on the screen. I can't 9 remember if I made changes based on what was on the 10 screen or if I just got on the phone and the changes 11 were made then.</p> <p>12 Q. But you are pretty sure you didn't print 13 it out and make handwritten comments on it?</p> <p>14 A. Right, right. Yes.</p> <p>15 Q. Let me ask you a better question: Did you 16 print out the e-mail that Sal sent you of the initial 17 draft of the report and then make handwritten comments 18 on it?</p> <p>19 A. No.</p> <p>20 Q. Do you remember when you signed the 21 report?</p> <p>22 A. Without looking at any data on it, I don't 23 have a specific.</p> <p>24 Q. Feel free to look at the data.</p> <p>25 A. Okay.</p>	<p>29</p> <p>1 you review any documents concerning this case?</p> <p>2 A. No.</p> <p>3 Q. Other than Sal, did you speak with anybody 4 else about the preparation of Exhibit 232?</p> <p>5 A. No.</p> <p>6 Q. Did you speak to Dr. Mukherjee with 7 respect to preparing Exhibit Number 232?</p> <p>8 A. No.</p> <p>9 Q. Did you speak to any Arthrex employee in 10 preparing Exhibit 232?</p> <p>11 A. No.</p> <p>12 Q. With respect to this present case, have 13 you ever spoken to Dr. Mukherjee?</p> <p>14 A. No.</p> <p>15 Q. With respect to this present case, have 16 you ever had any communications with Dr. Mukherjee?</p> <p>17 A. No.</p> <p>18 Q. No e-mails?</p> <p>19 A. I don't know Dr. Mukherjee.</p> <p>20 Q. How did you prepare for today's 21 deposition, Dr. Burks?</p> <p>22 A. I had a meeting with Sal Tamburo.</p> <p>23 Q. Anything else?</p> <p>24 A. No.</p> <p>25 Q. When did you meet with Sal Tamburo for</p>

8 (Pages 26 to 29)

<p style="text-align: right;">30</p> <p>1 preparation of today's deposition?</p> <p>2 A. Last night.</p> <p>3 Q. Where did you meet?</p> <p>4 A. Here.</p> <p>5 Q. At the hotel?</p> <p>6 A. Yes.</p> <p>7 Q. For about how long did you meet with Sal</p> <p>8 in preparation for today's deposition?</p> <p>9 A. Two hours.</p> <p>10 Q. Did you have a chance to speak with Mr.</p> <p>11 Tamburo today about preparing for today's deposition?</p> <p>12 A. No.</p> <p>13 Q. When you met with Mr. Tamburo last night</p> <p>14 for about two hours, what did you discuss?</p> <p>15 A. We talked about the report, talked about</p> <p>16 basics on depositions, that it would be a video</p> <p>17 deposition, etc. I can't remember, really, any other</p> <p>18 specifics.</p> <p>19 Q. What did you talk about when you talked</p> <p>20 about the report?</p> <p>21 A. I think it was more just what probably</p> <p>22 would be the basis of questions, i.e., background,</p> <p>23 questions of, you know, how things were done,</p> <p>24 questions of relationships, things like that.</p> <p>25 Q. When you say "how things were done", what</p>	<p style="text-align: right;">32</p> <p>1 where it needs to be visible.</p> <p>2 Q. Continue.</p> <p>3 A. What else would be important to me? Size</p> <p>4 of the suture is important, obviously.</p> <p>5 Q. I'm sorry, just so we're on the same page.</p> <p>6 my question was not directed to what's important to</p> <p>7 you but what's important to an orthopedic surgeon as</p> <p>8 written in paragraph six of your report. Exhibit 232.</p> <p>9 A. Okay. I'm an orthopedic surgeon so I was</p> <p>10 thinking what would be important to me and what would</p> <p>11 be important to other orthopedic surgeons.</p> <p>12 Q. Okay. So what you wrote in Exhibit 232,</p> <p>13 paragraph six, the first sentence, it says: "I may</p> <p>14 describe the characteristics of a surgical suture that</p> <p>15 are generally important to an orthopedic surgeon."</p> <p>16 When you say "to an orthopedic surgeon"</p> <p>17 there, are you referring to a generic orthopedic</p> <p>18 surgeon or are you referring to yourself?</p> <p>19 A. I would say my opinion of those</p> <p>20 characteristics for an orthopedic surgeon, of which I</p> <p>21 am one.</p> <p>22 Q. So those characteristics are generally</p> <p>23 important to you or to another orthopedic surgeon?</p> <p>24 A. I think both.</p> <p>25 Q. Because there's some things that you might</p>
<p style="text-align: right;">31</p> <p>1 are you referring to?</p> <p>2 A. Just methods of looking at the suture.</p> <p>3 Q. And how you performed the tests?</p> <p>4 A. Uh-huh.</p> <p>5 Q. Dr. Burks, could you please turn to</p> <p>6 paragraph six in Exhibit 232. Are you there?</p> <p>7 A. Yes.</p> <p>8 Q. Can you please describe the</p> <p>9 characteristics of a surgical suture that are</p> <p>10 generally important to an orthopedic surgeon?</p> <p>11 A. I think importance would be that it's</p> <p>12 compatible with the body so that there aren't</p> <p>13 significant reactions, strength.</p> <p>14 Q. You mean biological reactions?</p> <p>15 A. Yes. Strength of the suture is important,</p> <p>16 how a suture handles, passes through tissue and ties</p> <p>17 is important.</p> <p>18 Q. Anything else?</p> <p>19 A. Probably hundreds, but that will cover it.</p> <p>20 Q. Other than compatible with the body,</p> <p>21 strength, handles well and passes through the tissue,</p> <p>22 sitting here right now can you tell me any other</p> <p>23 characteristics of a surgical suture that are</p> <p>24 generally important to an orthopedic surgeon?</p> <p>25 A. Sure. There are certain circumstances</p>	<p style="text-align: right;">33</p> <p>1 consider important but another orthopedic surgeon</p> <p>2 might not consider important, is that right?</p> <p>3 A. That would be true.</p> <p>4 Q. So then in first sentence of paragraph</p> <p>5 six -- I'm still trying to understand -- you may</p> <p>6 describe characteristics of a surgical suture that are</p> <p>7 generally important to you or to another orthopedic</p> <p>8 surgeon?</p> <p>9 A. I would describe what my experience would</p> <p>10 tell me that most orthopedic surgeons feel is</p> <p>11 important and what I also feel.</p> <p>12 Q. Now, when you say "my experience would</p> <p>13 tell me that most orthopedic surgeons feel", what is</p> <p>14 that experience based on?</p> <p>15 A. It's based on over 25 years of doing this.</p> <p>16 Q. Okay. Is that experience based on any</p> <p>17 surveys you've read or conversations you've had with</p> <p>18 other orthopedic surgeons where they've told you that</p> <p>19 they think these particular characteristics of a</p> <p>20 surgical suture are important?</p> <p>21 A. I don't know that I could specifically</p> <p>22 relate to surveys but, certainly, there are</p> <p>23 conversations and discussions about it.</p> <p>24 Q. Have you read any surveys describing the</p> <p>25 characteristics of a surgical suture that are</p>

<p>34</p> <p>1 generally important to an orthopedic surgeon?</p> <p>2 A. Not that I remember.</p> <p>3 Q. Have you conducted any surveys describing</p> <p>4 the characteristics of a surgical suture that are</p> <p>5 generally important to orthopedic surgeons?</p> <p>6 A. No.</p> <p>7 Q. Other than compatibility with the body,</p> <p>8 strength, handling, passing through tissue and size,</p> <p>9 are there any other characteristics of a surgical</p> <p>10 suture that are generally important to an orthopedic</p> <p>11 surgeon?</p> <p>12 A. I also mentioned knot tying.</p> <p>13 Q. Is knot security an important</p> <p>14 characteristic of a surgical suture?</p> <p>15 A. Sure.</p> <p>16 Q. Why is that?</p> <p>17 A. Well, if you tie a knot you intend to have</p> <p>18 a suture have a certain amount of tension in it and if</p> <p>19 you don't have knot security, you probably won't have</p> <p>20 that tension.</p> <p>21 Q. Anything else?</p> <p>22 A. No.</p> <p>23 Q. Is knot strength an important</p> <p>24 characteristic of a surgical suture?</p> <p>25 A. Sure.</p>	<p>36</p> <p>1 A. Sure.</p> <p>2 MR. TAMBURRO: Objection: considered by Dr.</p> <p>3 Burks or who?</p> <p>4 Q. I think he can only testify for himself.</p> <p>5 So based on your opinion, the answer is the same?</p> <p>6 A. Sure.</p> <p>7 Q. All things being equal, a suture that has</p> <p>8 a lower knot profile would be considered advantageous</p> <p>9 over a suture that had a higher knot profile, is that</p> <p>10 generally correct?</p> <p>11 A. If one were to say all other things are</p> <p>12 equal, then sure.</p> <p>13 Q. Based on your experience in orthopedic</p> <p>14 surgery is it better to have fewer knots in a suture</p> <p>15 when performing surgery?</p> <p>16 A. You might have to work on that one again.</p> <p>17 I was just going to get a clarification of the</p> <p>18 question.</p> <p>19 Q. We'll come back to that one. You said</p> <p>20 strength is an important characteristic of a surgical</p> <p>21 suture; why is that?</p> <p>22 A. If the suture breaks, it doesn't do you</p> <p>23 any good.</p> <p>24 Q. Anything else?</p> <p>25 A. No.</p>
<p>35</p> <p>1 Q. Why?</p> <p>2 A. Same.</p> <p>3 Q. Same as what?</p> <p>4 A. Same as what I just said.</p> <p>5 Q. Do you know what the term "knot profile"</p> <p>6 means?</p> <p>7 A. I think I do.</p> <p>8 Q. What's your understanding of the term knot</p> <p>9 profile?</p> <p>10 A. My understanding would be after a knot is</p> <p>11 tied, the suture frequently is wrapped around itself.</p> <p>12 And knot profile would be how large that knot</p> <p>13 generally appears after the knot has been tied and</p> <p>14 cut.</p> <p>15 Q. Is knot profile and knot height considered</p> <p>16 the same thing, based on your experience?</p> <p>17 A. I suppose they could be fairly close.</p> <p>18 Q. Is knot height and knot profile an</p> <p>19 important characteristic of a surgical suture?</p> <p>20 A. I think it would be fairly low on the</p> <p>21 grade if you were to mark it.</p> <p>22 Q. Is it considered an important</p> <p>23 characteristic of a surgical suture? Is knot height</p> <p>24 and knot profile considered important characteristics</p> <p>25 of a surgical suture?</p>	<p>37</p> <p>1 Q. You also said that handling is an</p> <p>2 important characteristic of a surgical suture?</p> <p>3 A. Sure.</p> <p>4 Q. Why is that?</p> <p>5 A. If you imagine trying to sew a suture</p> <p>6 together with a lead wire, it would make it much more</p> <p>7 difficult. So having flexibility and maneuvering is</p> <p>8 important.</p> <p>9 Q. As you use the term "handling", what are</p> <p>10 you referring to?</p> <p>11 A. The ability to manipulate a suture, to</p> <p>12 place a suture where you would like it to be, to be</p> <p>13 able to pull it together to tie knots.</p> <p>14 Q. Anything else?</p> <p>15 A. No.</p> <p>16 Q. You also said that passing through tissue</p> <p>17 is considered an important characteristic of a</p> <p>18 surgical suture. Why is that?</p> <p>19 A. Some tissues are more delicate or maybe</p> <p>20 more damaged in a way that if a suture doesn't pass</p> <p>21 through well and it takes sawing back and forth or</p> <p>22 pulling, it might damage the tissue you are trying to</p> <p>23 repair.</p> <p>24 Q. You also said visibility is an important</p> <p>25 characteristic of a surgical suture. Why is that?</p>

10 (Pages 34 to 37)

<p>38</p> <p>1 A. If you are putting sutures into a 2 structure to fix it and you tie one down and can't 3 really see where it is, you may not know how to place 4 your next suture relative to the first one. 5 Q. In your experience, what makes a surgical 6 suture more visible than another? 7 A. Color. 8 Q. Anything else? 9 A. I think mostly color. 10 Q. Are you familiar with the suture knot 11 configurations identified by number, like a two -- two 12 equals two or three equals two equals one or four 13 equals one equals one? Is that nomenclature -- do you 14 understand that? 15 A. I'm not -- I would answer that by saying 16 I'm not sure. I think I know what you are talking 17 about. 18 Q. What do you think I'm talking about? 19 A. Well, sometimes when people tie knots and 20 they talk about how many half hitches they may place 21 in a knot they may say you put two one way, one 22 another way and two another way and it may be sort of 23 an two-one-two or something. 24 I'm not sure if that's how you are meaning 25 it, but I've seen that before.</p>	<p>40</p> <p>1 you mean by size? 2 A. Diameter. 3 Q. Why is that important? 4 A. Well, if I was to take a shoe string and 5 try to sew your eyelid, that would probably be a 6 problem. 7 Q. Did does that mean the smaller the 8 diameter the better? 9 A. No. 10 Q. Can you explain that then. 11 A. It means that diameter should be 12 appropriate for the location that a suture is being 13 used and the requirements that you are placing on it. 14 Q. For a given procedure, do you have a 15 certain number of half hitches you use when tying a 16 knot? 17 A. No. 18 Q. It varies? 19 A. Yes. 20 Q. It varies on what? 21 A. My per -- 22 Q. Go ahead, I'm sorry. 23 A. My perception of how well I've tied the 24 half hitches before, and so I may be doing something 25 that I think I didn't reverse it right or didn't make</p>
<p>39</p> <p>1 Q. In that situation would a knot with less 2 half hitches be considered better than a knot that has 3 more half hitches? 4 A. No. 5 Q. Why not? 6 A. Well, the first important thing we talked 7 about is the security. So, for example, I could throw 8 one half hitch which would be fewer half hitches but 9 that knot won't hold. So fewer is not necessarily 10 better. 11 Q. Assuming that two knots have the same knot 12 security, would the knot with the fewer amount of 13 throws be considered better? 14 A. I don't think I'd necessarily say that. 15 Q. Why not? 16 A. I think the main thing that's important is 17 that the knot holds what it's supposed to hold. I 18 think the extra throw or two is so minor that it's 19 many times hard to know is three enough, is four 20 enough, is five enough? We may say we don't want to 21 take any chances and put one or two more in. 22 So I don't think it's too important 23 whether you do that or not. 24 Q. You also said size was an important 25 characteristic of a surgical suture. First, what do</p>	<p>41</p> <p>1 it as tight and I want or whatever so I might want to 2 throw more half hitches on it. 3 Q. For a given procedure, what are the ranges 4 of number of half hitches you throw in a knot -- is 5 that right? 6 A. Sure. The number would vary very largely 7 because when we tie arthroscopically we many times use 8 a complex knot as the first knot so it's not just a 9 half hitch. But sometimes you can't do that and so you 10 do have to just use half hitches. So if you are only 11 doing half hitches, obviously, you would throw several 12 on. 13 If you are doing a complex knot, then you 14 may not need as many half hitches to back it up. 15 Q. When you say "complex knot" is that a 16 particular knot or are you just referring to -- 17 A. Yes. 18 Q. That's a particular knot configuration? 19 A. Correct. 20 Q. And you've heard the term surgeon's knot? 21 A. Yes. 22 Q. What is a surgeon's knot? 23 A. Well, surgeon's is simply like a half 24 hitch throw only you throw it twice so that you have 25 more friction between the suture when you are trying</p>

42

1 to apply tension.

2 Q. Is that different than a square knot?

3 A. Yes.

4 Q. What's a square knot?

5 A. Describe a square knot. It's an
6 over-under-under-over half hitch throw. A surgeon's
7 knot is not a knot from the standpoint of a final
8 product.

9 So a square knot -- when you tie a square
10 knot you could argue you have a final product. You are
11 not as done. But with a surgeon's throw, all you are
12 doing is making it tighter so that you can now throw
13 another throw to help finish the knot and lock it in
14 place.

15 Q. What is a throw?

16 A. Like a half hitch.

17 Q. What is a half hitch?

18 A. It's taking suture and looping it around
19 the other limb of the suture.

20 Q. Is it similar to tying a shoe, the first
21 part of tying a shoe? Do you understand what I'm
22 saying?

23 A. Yes. Actually, if you are tying a shoe,
24 for the first throw if you did it twice and pulled it,
25 that's a surgeon's. And so that's what that means.

44

1 you have knot security without taking the extra time

2 to throw extra half hitches that maybe are not helping
3 you.

4 Q. So the goal is to secure the knot,
5 correct?

6 A. Correct.

7 Q. What's the disadvantage of throwing ten
8 half hitches versus only throwing five half hitches?

9 A. My time.

10 Q. Anything else?

11 A. Patient's time.

12 Q. Anything else?

13 A. All our time.

14 Q. Anything else? Is there a medical reason
15 why you wouldn't use ten half hitches or five half
16 hitches?

17 A. No.

18 Q. Does it affect the patient? Does it take
19 up real estate in the body?

20 A. Well, clearly, if you were talking about
21 the entire human body there are places where, clearly,
22 taking up real estate could be a problem.

23 Q. I'm talking about shoulders.

24 A. Right. I don't think there's much that I
25 do that that's a big concern. But I think you are

43

1 So the single throw can be a half hitch
2 but, obviously, when you tie your shoe, you lay it
3 down a little flatter than what we do when we operate.

4 Q. For a given knot, what is the range of
5 number of half hitches you throw?

6 MR. TAMBURIO: Objection, vague.

7 A. If I throw a complex knot, then I usually
8 put two to four half hitches behind it. If I can't
9 throw a complex knot and I'm just throwing half
10 hitches, then I probably would be in the six to seven
11 range.

12 Q. The purposes of the two to four half
13 hitches behind the complex knot, is that to hold the
14 complex knot?

15 A. Correct.

16 Q. And then when you just do six to seven
17 half hitches that's just -- that's its own that holds
18 itself?

19 A. Correct.

20 Q. Why not do more than six to seven half
21 hitches or more than two to four half hitches behind a
22 complex knot?

23 A. There have been studies done on multiple
24 different types of knots and backing it up. And I
25 think that that is a reasonable number to be safe that

45

1 asking why not do ten or 12 and, clearly, you could
2 get to the ridiculous and have a rope braided and
3 there's no point in that.

4 MR. TAMBURIO: When you get to a convenient
5 point.

6 Q. (By Mr. Falke) Does having too many half
7 hitches in the body or too many throws in the body
8 delay healing of the tissue?

9 A. No.

10 MR. FALKE: Let's take a break.

11 THE VIDEOGRAPHER: Off record, 4:08.
12 (Brief recess.)

13 THE VIDEOGRAPHER: On the record, 4:21.

14 Q. Dr. Burks, in Exhibit 232, paragraph six,
15 you state: "I may also describe the specific features
16 of FiberWire that I find beneficial in my practice";
17 do you see that?

18 A. Yes.

19 Q. Would you describe the specific features
20 of FiberWire that you find important?

21 A. I think the most important feature is its
22 strength, so that it's difficult to break.

23 Q. Other than strength, what are the specific
24 features of FiberWire that you find beneficial?

25 A. Well, I think it provides many of the

<p style="text-align: right;">46</p> <p>1 other features that we talked about that you'd like to 2 see in a suture but it does it in a way that it is a 3 very strong suture which makes it much easier to work 4 with. 5 Q. What other features that we talked about 6 apply to FiberWire that you find beneficial? 7 A. I guess what I'm meaning is that the 8 features we talked about such a handleability, passing 9 through tissue, knot tying, etc.. I find those 10 features to be good, but what distinguishes it for me 11 primarily is its strength. 12 Q. I'm just trying to be specific here. You 13 said handleability, passing through tissue, knot 14 tying, etc. When you say "etc.", what other features 15 that we talked about apply to FiberWire? 16 A. I would say all the features that we 17 talked about that you got done writing down. If 18 FiberWire didn't meet those, then its strength might 19 not be important; but since it does meet those and it 20 is stronger than other sutures, then it becomes a 21 preference. 22 Q. What suture did you use before FiberWire 23 came onto the market? 24 A. For permanent suture we primarily used 25 Ethibond.</p>	<p style="text-align: right;">48</p> <p>1 Q. Have you ever used OrthoCord? 2 A. Yes. 3 Q. When have you used Herculine? 4 A. Herculine is a Linvitek product and so if 5 I use a Linvitek anchor the Herculine comes with it 6 and so that would usually be the time I'd use it. 7 Q. When do you use OrthoCord? 8 A. Same thing. OrthoCord is a Mitek product 9 so if I use that I usually get the OrthoCord with it. 10 I sometimes use three strands of OrthoCord when I 11 don't need an anchor and I'm just sewing two tissues 12 together. 13 Q. Do you like OrthoCord? 14 A. Yes. 15 Q. Why do you like OrthoCord? 16 A. I think for the same reason I like 17 FiberWire. It's a very strong, hard-to-break suture. 18 Q. Does OrthoCord also have the 19 characteristics of good handleability? 20 A. Yes. 21 Q. Does OrthoCord also have the 22 characteristics of passing through suture well? 23 A. Yes. 24 Q. Does OrthoCord tie knots well? 25 A. Yes.</p>
<p style="text-align: right;">47</p> <p>1 Q. Let me rephrase the question. What suture 2 did FiberWire wire replace in your practice? 3 A. It replaced Ethibond. 4 Q. Anything else? 5 A. Well, there are other companies that make 6 sutures that are like Ethibond. Ethibond is almost 7 like Kleenex where you say Ethibond and you actually 8 might be using a suture from another company but we 9 call it Ethibond. But that's primarily what it 10 replaced. 11 Q. Is Ethibond manufactured by Ethicon? 12 A. Yes, but due to suture costs and bidding 13 wars, there are other companies that make similar to 14 Ethibond-type suture and we may have used those as 15 well in the past. 16 Q. Is FiberWire stronger than Herculine? 17 A. I don't know the answer to that. 18 Q. Is FiberWire stronger than MaxBraid? 19 A. I don't know. 20 Q. Is FiberWire stronger than OrthoCord? 21 A. I don't know. 22 Q. Have you ever used Herculine? 23 A. I have. 24 Q. Have you ever used MaxBraid? 25 A. No.</p>	<p style="text-align: right;">49</p> <p>1 Q. Does it have good knot security? 2 A. Yes. 3 Q. Does it have good knot strength? 4 A. Yes. 5 Q. If we could turn to paragraph seven, 6 please, in Exhibit 232. Are you there? 7 A. I am. 8 Q. You state: "I've been using FiberWire 9 suture in my surgical procedures since 2001." What 10 surgical procedures do you use FiberWire in? 11 A. I use FiberWire in most of the surgical 12 procedures I do. 13 Q. Which ones are they? 14 A. I use it with shoulder replacement. I use 15 it with rotator cuff repair. I use it with shoulder 16 instability, knee ligament surgery. 17 Q. What knee ligament surgery do you use 18 FiberWire in? 19 A. We use FiberWire whenever we want to 20 repair torn ligaments back down to bone. 21 Q. You also say in exhibit seven of 232: 22 "Most of my subjective use of FiberWire occurs during 23 surgery and in the surgical environment. FiberWire is 24 generally wet." 25 What do you mean by "subjective use"?</p>

<p style="text-align: right;">50</p> <p>1 A. Poor wording. I guess it was to say that 2 my sense of how FiberWire works and handles, that 3 subjective feel of that is in that environment. 4 Q. So you don't use FiberWire in any 5 non-surgical environment, do you? 6 A. Well, I've used FiberWire in laboratory 7 studies when we do cadaveric studies or other things. 8 But I don't use it for non-medically related things. 9 Q. When you say "most of my subjective use of 10 FiberWire occurs during surgery", were you referring 11 to the surgical environment versus non-surgical 12 environment like you just described? 13 A. Right. 14 Q. Then you say "FiberWire is generally wet 15 in the surgical environment", what does that mean? 16 A. Well, in the environment where I work 17 arthroscopically we work with fluids, so it's hard for 18 a suture not to be wet. 19 Obviously, there are times where we work 20 in a dry air environment and the suture may get wet 21 passing through tissue, but it's not necessarily 22 intentionally wetted like it is with arthroscopy. 23 Q. During surgery, do you wet FiberWire 24 before it's introduced into the body? 25 A. Not deliberately, no.</p>	<p style="text-align: right;">52</p> <p>1 determines whether you wear gloves? 2 A. In a nonsurgical environment it would be 3 protection for me. 4 Q. Okay. Protection from what? 5 A. Well, if we do cadaveric surgery some 6 cadavers have diseases so we may want to have gloves 7 on when we work with them. 8 Q. What about in the laboratory environment, 9 when you are using FiberWire, do you wear gloves? 10 A. I guess it depends on what you mean by the 11 laboratory environment. 12 Q. By laboratory environment, I mean anything 13 other than a surgical or nonsurgical environment like 14 we've been talking about. 15 A. Well, we do, for example, cadaveric 16 surgery in the laboratory, so we would consider that a 17 laboratory environment, and I would use gloves for 18 self-protection in that setting. 19 Q. Let me ask you a better question. Outside 20 of a surgical environment or nonsurgical environment, 21 do you wear gloves when using FiberWire? 22 A. I guess I would say no. 23 Q. Dr. Burks, if you could turn in Exhibit 24 232 to paragraph eight, you state: "Sometime in 25 February 2006 I was contacted by attorneys for</p>
<p style="text-align: right;">51</p> <p>1 Q. Earlier you said the suture may get wet 2 passing through tissue, but it's not necessarily 3 intentionally like it is with arthroscopy. I don't 4 know what that means. 5 A. In an arthroscopic environment we have a 6 microscope in a joint and we distend the joint so we 7 can see with fluid. 8 So any time we introduce suture into that 9 environment it's under water, if you will. So no 10 matter what we do with it, by the time we start to use 11 it, it's wet. 12 Q. When using FiberWire in a surgical 13 environment, do you always wear gloves? 14 A. Yes. 15 Q. What about in the -- let me rephrase the 16 question. In a nonsurgical environment, do you always 17 wear gloves when using FiberWire? 18 A. No. 19 Q. What determines whether you wear gloves? 20 A. Either sterility for a patient or 21 protection for myself. 22 Q. If it's a nonsurgical environment, how 23 does sterility of the patient matter? 24 A. It doesn't. 25 Q. In a nonsurgical environment, what</p>	<p style="text-align: right;">53</p> <p>1 Arthrex, Inc., and asked to conduct a tactile feel 2 analysis as well as a knot tie-down analysis of coated 3 and uncoated FiberWire suture. I agreed to conduct the 4 analysis." Do you see that? 5 A. I do. 6 Q. Who contacted you in February of 2006? 7 A. Sal Tamburo. 8 Q. Anyone else? 9 A. No. 10 Q. Do you remember the substance of the 11 conversation you had with Sal in February of 2006? 12 A. Yes. 13 Q. What was that substance? 14 A. He said that Arthrex and more, in 15 particular, FiberWire was involved in a patent 16 infringement lawsuit and he was wondering, since I've 17 had experience of using FiberWire, if I would be 18 willing to talk about FiberWire and how its used, 19 etc., and if I'd be willing to look at FiberWire in a 20 couple of different states and give him feedback on 21 what I thought about that. 22 Q. What were those couple different states? 23 A. My understanding was that it was a coated 24 suture and a not-coated suture. 25 Q. Anything else?</p>

14 (Pages 50 to 53)

<p>54</p> <p>1 A. No.</p> <p>2 Q. Do you know why Sal contacted you as</p> <p>3 opposed to another orthopedic surgeon?</p> <p>4 A. No.</p> <p>5 Q. During the conversation you had with Sal</p> <p>6 in February of 2006, did he suggest that you conduct a</p> <p>7 tactile feel analysis and a knot tie-down analysis?</p> <p>8 A. Yes.</p> <p>9 Q. Did he suggest any other tests to do on</p> <p>10 coated and uncoated FiberWire suture?</p> <p>11 A. No.</p> <p>12 Q. Did you suggest any other test to perform</p> <p>13 at that time, in February of 2006?</p> <p>14 A. No.</p> <p>15 Q. At any time did you suggest doing a test</p> <p>16 other than a knot tie-down or tactile feel analysis</p> <p>17 for purposes of this litigation?</p> <p>18 A. No.</p> <p>19 Q. At any time did anyone suggest to you to</p> <p>20 do a test other than a knot tie-down or tactile feel</p> <p>21 analysis for purposes of this litigation?</p> <p>22 A. No.</p> <p>23 Q. Do you know why they suggested that you</p> <p>24 perform a tactile feel analysis and knot tie-down</p> <p>25 analysis?</p>	<p>56</p> <p>1 the coated or uncoated samples for purposes of this</p> <p>2 litigation?</p> <p>3 A. No.</p> <p>4 Q. Did Arthrex's attorneys or anyone provide</p> <p>5 you with any documents that helped you render any</p> <p>6 opinions expressed in Exhibit Number 232?</p> <p>7 A. No.</p> <p>8 Q. Did you read any deposition transcripts</p> <p>9 from this case for purposes of rendering your opinions</p> <p>10 in Exhibit Number 232?</p> <p>11 A. The only thing that I had looked at was</p> <p>12 back in paragraph five.</p> <p>13 Q. Dr. Fenton's report?</p> <p>14 A. Yeah, I had seen that but -- I don't</p> <p>15 specifically remember it -- but I had seen it at the</p> <p>16 time.</p> <p>17 Q. How did you see it?</p> <p>18 A. It was sent by Sal.</p> <p>19 Q. Other than Dr. Fenton's report, did you</p> <p>20 receive any other documents from anyone for purposes</p> <p>21 of rendering opinions in this case?</p> <p>22 A. No.</p> <p>23 Q. Prior to performing tests reflected in</p> <p>24 Exhibit Number 232, had you ever performed a tactile</p> <p>25 feel analysis on a coated and uncoated suture before</p>
<p>55</p> <p>1 A. Not specifically.</p> <p>2 Q. Generally do you know?</p> <p>3 A. Generally. My general perception is they</p> <p>4 were wanting to determine if the suture seemed</p> <p>5 different with one treatment versus another.</p> <p>6 Q. What do you mean by "seemed different"?</p> <p>7 A. Well, it was a subjective assessment on my</p> <p>8 part if it seemed like the sutures handled differently</p> <p>9 or tied differently.</p> <p>10 Q. Anything else?</p> <p>11 A. No.</p> <p>12 Q. Do you remember anything else from the</p> <p>13 conversation you had with Sal in February of 2006 when</p> <p>14 he called you and asked you to perform these tests?</p> <p>15 A. No.</p> <p>16 Q. So after that conversation, what was the</p> <p>17 scope of your assignment?</p> <p>18 A. I actually told Sal that it would be my</p> <p>19 preference that he send me these two sutures that, you</p> <p>20 know, without specific labeling and that I would then</p> <p>21 work with those two different specimens and call him</p> <p>22 back and say this is what my feelings are.</p> <p>23 Q. Uh-huh. Other than the tactile feel</p> <p>24 analysis and the knot tie-down analysis reported in</p> <p>25 Exhibit 232, did you perform any other tests the on</p>	<p>57</p> <p>1 Arthrex asked you to do it for purposes of this</p> <p>2 litigation?</p> <p>3 A. No.</p> <p>4 Q. Have you ever performed a knot tie-down</p> <p>5 analysis on a coated and uncoated suture before</p> <p>6 Arthrex asked you to do it for purposes of this</p> <p>7 litigation?</p> <p>8 A. No.</p> <p>9 Q. The tactile feel analysis that you</p> <p>10 performed, as reflected in Exhibit 232, is that a</p> <p>11 published test?</p> <p>12 A. No.</p> <p>13 Q. The tactile feel analysis that you</p> <p>14 performed, as reflected in Exhibit 232, was that a</p> <p>15 standard test?</p> <p>16 A. Not that I'm aware of.</p> <p>17 Q. So you are not aware of any publications</p> <p>18 describing the tactile feel analysis that you</p> <p>19 performed in Exhibit Number 232?</p> <p>20 A. No.</p> <p>21 Q. The knot tie-down analysis that you</p> <p>22 performed, as reflected in Exhibit 232, is that a</p> <p>23 published test?</p> <p>24 A. I would say I'm unaware.</p> <p>25 Q. Unaware of what?</p>

<p>58</p> <p>1 A. Unaware if it's a published test. I'm sure 2 there are some industry standard tests that get done 3 on sutures. but I don't specifically know what those 4 tests are.</p> <p>5 Q. The knot tie-down analysis that you 6 performed, as reflected in Exhibit 232, is that a 7 standard test?</p> <p>8 A. No.</p> <p>9 Q. Have you ever used an uncoated suture 10 during surgery?</p> <p>11 A. I would think I probably have.</p> <p>12 Q. Why do you say that?</p> <p>13 A. I would say over the years we've used an 14 awful lot of different types of sutures, and my best 15 guess would be that there are some that don't have a 16 coating or some other treatment.</p> <p>17 Q. Can you specifically recall ever using an 18 uncoated suture in a surgical environment?</p> <p>19 A. I guess I would answer that by saying I'm 20 uncertain. If we had a list right now of sutures that 21 would be considered uncoated, I probably would say oh, 22 yeah, I've used three or four of those. but I can't 23 give you a specific knowledgeable answer.</p> <p>24 Q. Do you know of any uncoated sutures that 25 are currently on the market?</p>	<p>60</p> <p>1 doesn't mean anything to me.</p> <p>2 Q. Between February of 2006, the initial 3 conversation you had with Sal, and March 2006 when you 4 had the samples, how many conversations did you have 5 with any Arthrex attorney?</p> <p>6 A. Either zero or maybe one to say, hey, the 7 suture is coming and it will be there next week or 8 something.</p> <p>9 Q. You just said when Sal mentioned that 10 there would be somebody in California sending you the 11 sutures, did that happen in the initial conversation 12 or did that happen in a conversation after the initial 13 February 2006 conversation?</p> <p>14 A. In the initial February 2006, I don't 15 think there was a mention of suture being sent. I 16 think it would be a subsequent that the suture was 17 being sent.</p> <p>18 Q. Do you remember anything from the 19 subsequent conversation -- do you remember anything 20 from the conversation after the initial February 2006 21 conversation but before you received the sutures in 22 March of 2006?</p> <p>23 A. Only that there was a conversation about 24 timing of when the suture might get sent or something.</p> <p>25 Q. Did you physically -- what physically did</p>
<p>59</p> <p>1 A. I think there may be many sutures that 2 don't have coating.</p> <p>3 Q. Do you know of any uncoated sutures that 4 are currently on the market?</p> <p>5 A. I wouldn't be able to say "I know this is 6 an uncoated suture", no.</p> <p>7 Q. Can you specifically name any uncoated 8 suture that you've used in a surgical environment?</p> <p>9 A. No.</p> <p>10 Q. Moving on to paragraph nine of Exhibit 11 232, you state: "In March 2006 I received two samples 12 of suture labeled suture A and suture B. Each sample 13 was on a spool and was approximately three meters in 14 length." Do you see that?</p> <p>15 A. I do.</p> <p>16 Q. Who sent you the two samples you refer to 17 in paragraph nine of Exhibit 232?</p> <p>18 A. I believe I received them from a company 19 in California.</p> <p>20 Q. Do you know the name of that company?</p> <p>21 A. I don't.</p> <p>22 Q. Does the name CETR mean anything to you?</p> <p>23 A. Only in that -- I think that Sal had 24 mentioned that they had done tests or had been 25 somewhat involved with the suture, but it otherwise</p>	<p>61</p> <p>1 you receive from the California company when you 2 received the two samples?</p> <p>3 A. I received a plastic bag with a sort of 4 enlarged spool, if you will, that had some suture on 5 it that said sample A and a similar way for one that 6 said sample B.</p> <p>7 Q. Were there two plastic bags each 8 containing one bag of suture?</p> <p>9 A. Yes.</p> <p>10 Q. Anything else?</p> <p>11 A. Packing material.</p> <p>12 Q. What was on the spools?</p> <p>13 A. Just, you know, a length of suture.</p> <p>14 Q. Let me rephrase the question. What 15 markings were on the spools that you received in March 16 2006?</p> <p>17 A. Just sample A, sample B.</p> <p>18 Q. Was that handwritten?</p> <p>19 A. My recollection would be that it was, but 20 I'm not sure.</p> <p>21 Q. Do you know whose handwriting that was?</p> <p>22 A. No.</p> <p>23 Q. Did it say "Pearsalls" on the spool?</p> <p>24 A. I don't remember that.</p> <p>25 Q. Other than sample A and sample B, can you</p>

16 (Pages 58 to 61)

<p>62</p> <p>1 remember any other marking on the spools?</p> <p>2 A. No.</p> <p>3 Q. Do you know who put the samples on the</p> <p>4 spools that you received in March 2006?</p> <p>5 A. No.</p> <p>6 Q. Could it be that there were other markings</p> <p>7 on the spools other than suture A and suture B?</p> <p>8 MR. TAMBURO: Objection, asked and</p> <p>9 answered.</p> <p>10 A. Certainly there could have been, you know.</p> <p>11 some marking or name. but I don't remember anything</p> <p>12 else that would be pertinent.</p> <p>13 Q. When you received the samples in March</p> <p>14 2006, did you have any indication of whether suture A</p> <p>15 or suture B was coated or uncoated?</p> <p>16 A. No.</p> <p>17 Q. So once you received the samples in the</p> <p>18 two plastic bags on the spools, what did you do next?</p> <p>19 A. Took the suture out, cut the suture with</p> <p>20 just regular scissors to make some lengths, and sort</p> <p>21 of had an A pile and a B pile.</p> <p>22 Q. Where were you when you received the</p> <p>23 suture samples in March of 2006?</p> <p>24 A. I believe they came to my office.</p> <p>25 Q. Did you perform the test in Exhibit 232 at</p>	<p>64</p> <p>1 not told which sample was coated and which was</p> <p>2 uncoated.</p> <p>3 Other than the coated versus uncoated</p> <p>4 distinction, were you told of any other differences</p> <p>5 between the two samples?</p> <p>6 A. No.</p> <p>7 Q. Once you cut the sutures off the spools,</p> <p>8 what did you do with the spools?</p> <p>9 A. Ultimately I pitched them.</p> <p>10 Q. At home?</p> <p>11 A. Uh-huh.</p> <p>12 Q. You threw them away?</p> <p>13 A. Yes.</p> <p>14 Q. What about the plastic bags that were used</p> <p>15 to hold the suture samples?</p> <p>16 A. Same.</p> <p>17 Q. You threw them away?</p> <p>18 A. Uh-huh.</p> <p>19 Q. So you cut five samples from each spool,</p> <p>20 right?</p> <p>21 A. Correct.</p> <p>22 Q. So you had five strands of suture A and</p> <p>23 five strands of suture B each segregated into their</p> <p>24 own pile, right?</p> <p>25 A. Yes.</p>
<p>63</p> <p>1 your office or at home?</p> <p>2 A. I actually did it at home.</p> <p>3 Q. Did you do any tests at the office?</p> <p>4 A. No.</p> <p>5 Q. So you received the samples in the office</p> <p>6 and then brought them home?</p> <p>7 A. Yes.</p> <p>8 Q. Did you cut them at home?</p> <p>9 A. Yes.</p> <p>10 Q. And then after you cut them, how did you</p> <p>11 segregate suture A and suture B?</p> <p>12 A. I just put all the A's from the one spool</p> <p>13 in a single pile and the B's in a separate pile.</p> <p>14 Q. How long were the lengths of suture when</p> <p>15 you cut them off the spool?</p> <p>16 A. They were roughly a couple of feet.</p> <p>17 Q. Was there anybody else present when you</p> <p>18 performed the tests in Exhibit 232?</p> <p>19 A. No.</p> <p>20 Q. Was there anybody else present when you</p> <p>21 cut the samples off the spools?</p> <p>22 A. No.</p> <p>23 Q. It also says in paragraph nine: I was</p> <p>24 told by Arthrex's attorney that one sample was coated</p> <p>25 and that the other sample was uncoated; however, I was</p>	<p>65</p> <p>1 Q. What did you do next?</p> <p>2 A. I spent a little time taking different</p> <p>3 sutures from one pile or from the other pile and just</p> <p>4 looked at them, felt them, handled them to see if I</p> <p>5 could tell much difference between them.</p> <p>6 Then I put them around a small hook to be</p> <p>7 like a suture anchor environment, if you will, and I</p> <p>8 tied some knots down, some slip knots, to see how it</p> <p>9 would feel.</p> <p>10 Then I wet it, immersed the sutures, and</p> <p>11 tied again to see if I could tell much of a</p> <p>12 difference.</p> <p>13 Q. You said you spent a little time taking</p> <p>14 different sutures from one pile and the other and just</p> <p>15 looked at them, handled them, felt them to see if I</p> <p>16 could tell much difference between them.</p> <p>17 What you just described there, is that the</p> <p>18 tactile feel analysis that you performed as reflected</p> <p>19 in Exhibit 232?</p> <p>20 A. Yes.</p> <p>21 Q. About how long did it take to perform the</p> <p>22 tactile feel analysis as reflected in Exhibit 232 from</p> <p>23 the time you cut the sutures until the time you</p> <p>24 concluded that there was a difference between suture A</p> <p>25 and suture B??</p>

<p style="text-align: right;">66</p> <p>1 A. Ten, 15 minutes.</p> <p>2 Q. About how long did it take to perform the</p> <p>3 knot tie-down analysis as reflected in Exhibit 232</p> <p>4 from the time you cut the sutures off the spools until</p> <p>5 the time you concluded there was a difference between</p> <p>6 suture A and suture B?</p> <p>7 A. Maybe 45 minutes. Can we stop one second?</p> <p>8 MR. FALKE: Sure.</p> <p>9 THE VIDEOGRAPHER: Off the record, 4:52.</p> <p>10 (Discussion off the record.)</p> <p>11 THE VIDEOGRAPHER: On the record, 4:56.</p> <p>12 Q. (By Mr. Falke) Can you please describe the</p> <p>13 tactile field analysis as shown in paragraph 11 of</p> <p>14 Exhibit 232?</p> <p>15 A. Well, it was a very subjective test of</p> <p>16 taking the suture and running it through the</p> <p>17 fingertips and pulling it back and forth. Nothing</p> <p>18 fancy.</p> <p>19 Q. Other than running it through your</p> <p>20 fingertips and pulling it back and forth, did you do</p> <p>21 anything else in the tactile feel analysis?</p> <p>22 A. No.</p> <p>23 Q. How many times did you perform the tactile</p> <p>24 feel analysis in Exhibit 232, paragraph 11?</p> <p>25 A. I'm not sure I could give you a specific</p>	<p style="text-align: right;">68</p> <p>1 the suture?</p> <p>2 A. I guess I assumed that a coating would</p> <p>3 make it smoother.</p> <p>4 Q. Anything else?</p> <p>5 A. No.</p> <p>6 Q. In the tactile feel analysis, which you</p> <p>7 just described, it sounds like what you described was</p> <p>8 just in the dry environment, is that correct?</p> <p>9 A. That part, yes.</p> <p>10 Q. Did you perform the tactile feel analysis</p> <p>11 in a wet environment as well?</p> <p>12 A. No, it was more knot-tying.</p> <p>13 Q. So you did not test FiberWire in a wet</p> <p>14 environment in the tactile feel analysis in Exhibit</p> <p>15 Number 232?</p> <p>16 A. No.</p> <p>17 Q. But in paragraph 11 it says: "The</p> <p>18 difference between the two samples was even more</p> <p>19 pronounced when they were wet, which is how I'm</p> <p>20 accustomed to using FiberWire"?</p> <p>21 A. Yes. That is, when you are tying knots and</p> <p>22 you are doing it in the wet environment, then you're</p> <p>23 feeling the sutures.</p> <p>24 Q. Right, but if you look at paragraph 11 in</p> <p>25 Exhibit 232, paragraph 11 deals with the tactile feel</p>
<p style="text-align: right;">67</p> <p>1 answer on that from memory. I would say six to eight.</p> <p>2 Q. On each --</p> <p>3 A. On each sample set.</p> <p>4 Q. Okay. On each sample set or on each</p> <p>5 individual suture in the sample?</p> <p>6 A. I did not do each individual suture.</p> <p>7 Q. So you did not actually perform a tactile</p> <p>8 feel analysis on each of the five sutures in suture</p> <p>9 set A and suture set B?</p> <p>10 A. Probably that would be true.</p> <p>11 Q. So then you can't say for sure whether all</p> <p>12 of the five in suture A were generally smoother than</p> <p>13 the five in suture B, is that right?</p> <p>14 A. They all came from the same spool so the</p> <p>15 properties of one strand should be pretty similar to</p> <p>16 the properties of the next strand.</p> <p>17 So the short answer would be yes, I didn't</p> <p>18 compare each strand but the strands I felt would be</p> <p>19 pretty representative coming from the same length.</p> <p>20 Q. You can't say for sure that all the five</p> <p>21 in A were smoother than all five in suture B?</p> <p>22 A. Correct.</p> <p>23 Q. Prior to performing the tactile feel</p> <p>24 analysis in Exhibit 232, did you have any preconceived</p> <p>25 impression of how the coating would affect the feel of</p>	<p style="text-align: right;">69</p> <p>1 analysis, right?</p> <p>2 A. Correct, so what I'm saying on the tactile</p> <p>3 feel analysis is I'm feeling it in a dry environment</p> <p>4 where I'm not doing anything with the suture, just</p> <p>5 feeling it in a dry environment. Then I feel it in</p> <p>6 the wet environment when I'm tying knots.</p> <p>7 Q. So in paragraph eleven when it says "was</p> <p>8 more pronounced when they were wet which is how I'm</p> <p>9 accustomed to using FiberWire" that's not true,</p> <p>10 though, right? You didn't perform --</p> <p>11 A. I think the confusion is maybe how I</p> <p>12 worded this. So when tying knots it's not -- I didn't</p> <p>13 view it personally as being totally separate of</p> <p>14 tactile over here and then a tactile over here.</p> <p>15 When you are tying the knot, you feel the</p> <p>16 suture and you are sliding the knot on it. That was</p> <p>17 part of my assessment when I'm tying the knot. It</p> <p>18 wasn't just laying it out and feeling it. It's a</p> <p>19 combination.</p> <p>20 Q. How do you know that the samples being wet</p> <p>21 was more pronounced in the tactile feel analysis if</p> <p>22 you did not do the tactile feel analysis on a wet</p> <p>23 suture?</p> <p>24 MR. TAMBURRO: Objection: asked and</p> <p>25 answered, mischaracterizes the testimony.</p>

18 (Pages 66 to 69)

<p>70</p> <p>1 A. I'll try to clarify again. I didn't, in my 2 mind, view it as a pure test A/test B. So when you 3 handle suture tying knots and doing things with it, 4 you have a tactile feel. So I didn't -- so that's part 5 of the knot tying. So I didn't segregate it out as two 6 isolated separate things.</p> <p>7 Q. So in your report, Exhibit 232, are you 8 making two conclusions based on a conclusion of the 9 tactile feel analysis and a conclusion based on the 10 knot tie-down analysis?</p> <p>11 A. I'll try to clarify again. A knot tie-down 12 analysis I view as having a tactile aspect to it as 13 well, you are feeling the suture as you tie it. So I 14 don't view them as totally isolated.</p> <p>15 Q. Okay. So how many analyses did you 16 perform as reflected in Exhibit 232?</p> <p>17 A. I used all the strands and tied multiple 18 knots on all the strands. So I'm not, I guess, quite 19 sure -- I can't tell you I did 20 knots on each strand 20 or 30, but they were each used for multiple knot 21 tying.</p> <p>22 Q. My question might have been unclear. Not 23 how many times did you perform the analysis, but how 24 many different analyses did you do in coming to the 25 conclusions as expressed in Exhibit Number 232?</p>	<p>72</p> <p>1 A. I tried to try knots partly with gloves to 2 see if I felt that there was a difference and partly 3 without gloves to see if I could feel a difference.</p> <p>4 Q. Did using gloves in the tests in Exhibit 5 232 affect your ability to distinguish between suture 6 A and suture B?</p> <p>7 A. I think, clearly, using gloves makes the 8 feel of the suture a little different. I guess I can't 9 answer directly to say if it makes the difference but, 10 yes, it probably makes a difference.</p> <p>11 Q. What difference does it make?</p> <p>12 A. You are covering your skin with the 13 gloves, so, you know, as you feel suture, your 14 absolute sensation of the suture probably changes 15 some.</p> <p>16 Q. Could you have reached the same 17 conclusions you reached in Exhibit 232 if you solely 18 used gloves in performing the tests?</p> <p>19 A. I didn't do it that way, so I guess I 20 can't answer that and say yes or no.</p> <p>21 Q. Did not using gloves help you to 22 distinguish between suture A and suture B?</p> <p>23 A. Potentially, yes.</p> <p>24 Q. Did it or -- I'm asking you if, in fact, 25 it did?</p>
<p>71</p> <p>1 MR. TAMBURRO: Objection, vague.</p> <p>2 A. I felt the suture and I tied knots with 3 the suture.</p> <p>4 Q. But earlier you testified that that's all 5 encompassed in the knot tie-down analysis. So I'm 6 wondering did you do a knot tie-down analysis and 7 that's it and that had two subparts or two different 8 analyses and then come up with a conclusion -- come up 9 with two different conclusions?</p> <p>10 MR. TAMBURRO: Objection, mischaracterizes 11 the testimony.</p> <p>12 A. Again, I'm not trying to characterize in 13 this that these are segregated separate tests, but 14 this was a tactile feel and knot tying. It was a 15 length subjective feel on both of those.</p> <p>16 So when you tie knots, you get a tactile 17 feel. So I was making the statement that on the 18 tactile feel, how it feels to me, it felt this way and 19 when I tied knots, it also felt that way. It's 20 sometimes hard to do one without doing the other.</p> <p>21 Q. When you were doing -- when you did the 22 tactile feel analysis and the knot tie-down analysis 23 as expressed in Exhibit 232 were you wearing gloves?</p> <p>24 A. Not always.</p> <p>25 Q. Can you explain the breakdown?</p>	<p>73</p> <p>1 A. And I'm telling you my answer is it 2 potentially did.</p> <p>3 Q. I don't think I understand that. How could 4 it potentially? I mean either it did or didn't, 5 right?</p> <p>6 A. No.</p> <p>7 MR. TAMBURRO: Objection, argumentative.</p> <p>8 Q. Why do you say "potentially"?</p> <p>9 A. I'm trying to be honest. I did feel 10 without gloves and I know there's a pile A and a pile 11 B, so there is potential that feeling suture without 12 gloves made me feel that A was a little different than 13 B that had I been gloved the entire time, I might not 14 have detected.</p> <p>15 Q. So from start to finish then after you cut 16 the suture samples until the time you made your 17 conclusions expressed in Exhibit Number 232, how long 18 was that?</p> <p>19 A. I'll give you the same answer: 45 minutes 20 or so.</p> <p>21 Q. So the 45 minutes encompassed roughly ten 22 minutes you spent on the tactile feel analysis?</p> <p>23 A. No.</p> <p>24 Q. So 45 minutes plus ten minutes or just 45 25 minutes?</p>

<p>74</p> <p>1 A. I would say it was probably 45 minutes 2 plus ten minutes.</p> <p>3 Q. Did you tie knots in each of the 4 individual five sutures from suture A and suture B?</p> <p>5 MR. TAMBURO: Objection, asked and 6 answered.</p> <p>7 A. Yes.</p> <p>8 Q. After you performed the tactile feel 9 analysis and knot tie-down, as reflected in Exhibit 10 232, what did you do with the sutures that you tested?</p> <p>11 A. I pitched them with the spools.</p> <p>12 Q. You threw them out?</p> <p>13 A. Yes.</p> <p>14 Q. Did counsel ever instruct you to not throw 15 away the samples?</p> <p>16 A. No.</p> <p>17 Q. Did counsel give you any instructions at 18 all what to do with the samples once you performed the 19 tests on them?</p> <p>20 A. No.</p> <p>21 Q. Did you throw them away at home or at the 22 office?</p> <p>23 A. At home.</p> <p>24 Q. And then once you completed the tactile 25 feel analysis and knot tie-down analysis and once you</p>	<p>76</p> <p>1 A. No.</p> <p>2 Q. What program do you use for your e-mails?</p> <p>3 A. At home it's a Comcast e-mail and then 4 here it's a Group-Wise.</p> <p>5 Q. But do you use -- what e-mailing system do 6 you use at home? Is it AOL or Lotus Notes or 7 Microsoft Outlook or a Yahoo account?</p> <p>8 A. It's a Comcast.</p> <p>9 Q. That's done on a personal computer?</p> <p>10 A. Yes.</p> <p>11 Q. What about in the office? What kind of 12 e-mailing system do you use?</p> <p>13 A. We call it Group-Wise.</p> <p>14 Q. Is the e-mail account you have at home 15 different than the one you have at the office?</p> <p>16 A. Uh-huh.</p> <p>17 Q. Did you look for the e-mail in response to 18 the subpoena, Exhibit Number 231?</p> <p>19 A. Yes. The e-mail -- I mean, my awareness 20 of the e-mails is that they go back two or three weeks 21 or so and then after that they just go into 22 cyberspace.</p> <p>23 Q. So you did not look for the e-mail in 24 response to the subpoena, Exhibit 231?</p> <p>25 A. No, because that was like three months</p>
<p>75</p> <p>1 threw away the sutures, what did you do next?</p> <p>2 A. Well, as it regards this, I sent an e-mail 3 to Sal and said here's what I thought.</p> <p>4 Q. Do you have a copy of that e-mail?</p> <p>5 A. Nope.</p> <p>6 Q. What did you do with the e-mail that you 7 sent to Sal after you concluded the tests?</p> <p>8 A. What did I do with the e-mail? I didn't do 9 anything with the e-mail. I hit "send".</p> <p>10 Q. It's still on your computer?</p> <p>11 A. I would doubt it's on the computer. I 12 mean, just due to the volume, they don't keep three 13 months or four months or whatever.</p> <p>14 Q. Did you send it from work or home, the 15 e-mail?</p> <p>16 A. I don't know for sure.</p> <p>17 Q. You don't know for sure?</p> <p>18 A. No.</p> <p>19 Q. Did you delete the e-mail you sent to Sal 20 after you finished performing the tests?</p> <p>21 A. I'm not sure I understand deleting the 22 e-mail. I sent him an e-mail. I didn't purposefully 23 delete any e-mail.</p> <p>24 Q. Do you use Microsoft Outlook for your 25 e-mails?</p>	<p>77</p> <p>1 ago.</p> <p>2 Q. When you say the e-mails go back two or 3 three weeks and then go into cyberspace, you are 4 referring to work e-mail or your home e-mail?</p> <p>5 A. Well, primarily, I guess I'm referring to 6 the work one. I don't use the home as much. So I 7 don't. . .</p> <p>8 Q. Do you remember what the e-mail said that 9 you wrote to Sal after you performed the tests in 10 Exhibit 232?</p> <p>11 A. Pretty much what's in here. I just said, 12 you know, sample A to me felt this way compared to 13 sample B.</p> <p>14 Q. Felt -- what word did you use to describe 15 how suture A felt in relationship to suture B?</p> <p>16 A. I don't remember specifically but, I mean, 17 I probably used a word like "smoother".</p> <p>18 Q. But you are not sure?</p> <p>19 A. I'm not sure of the word.</p> <p>20 Q. Did Sal send an e-mail back to you once 21 you sent him the e-mail after completing the tests in 22 Exhibit 232?</p> <p>23 A. Not that I remember specifically.</p> <p>24 Q. When was the next time you spoke to Sal 25 after sending the e-mail on which you completed the</p>

20 (Pages 74 to 77)

<p style="text-align: right;">78</p> <p>1 tests in Exhibit Number 232?</p> <p>2 A. Oh, boy. I don't remember specifically.</p> <p>3 Q. Do you remember what day you completed the</p> <p>4 tests in Exhibit 232?</p> <p>5 A. No.</p> <p>6 Q. Did you take any notes while doing the</p> <p>7 tests in Exhibit 232?</p> <p>8 A. I did not.</p> <p>9 Q. Do you remember how long -- what the time</p> <p>10 period was between completion of this report and</p> <p>11 completion of the tests?</p> <p>12 A. I don't honestly remember specifically. It</p> <p>13 seems to me that it was a shorter time because of time</p> <p>14 demands on the case.</p> <p>15 Q. Like two weeks or a week?</p> <p>16 A. Yeah. I'll guess in that range. I'm not</p> <p>17 sure.</p> <p>18 Q. So then once you sent the e-mail to Sal</p> <p>19 saying that you completed the tests and giving the</p> <p>20 conclusions you came to, what happened next?</p> <p>21 A. Probably nothing until Sal contacted me</p> <p>22 and said, you know, there's a report that we need to</p> <p>23 do on this, and, you know, we need a CV and we need</p> <p>24 other information and stuff like that.</p> <p>25 Q. What happened next?</p>	<p style="text-align: right;">80</p> <p>1 A. I think so.</p> <p>2 Q. And then you made some changes to the</p> <p>3 draft that Sal sent you, right?</p> <p>4 A. Yes.</p> <p>5 Q. And then you sent it back to Sal or you</p> <p>6 had a phone conversation with Sal, is that right?</p> <p>7 A. Yes.</p> <p>8 Q. And then did Sal send you another draft of</p> <p>9 the report after that conversation?</p> <p>10 A. Yeah.</p> <p>11 Q. And then what happened then?</p> <p>12 A. My recollection would be that, you know, I</p> <p>13 called him up and said it seems okay to me, and I</p> <p>14 signed it. And, again, I don't specifically remember</p> <p>15 how he got it back.</p> <p>16 Q. So it sounds like that there was at least</p> <p>17 one initial draft of the report, you made changes to</p> <p>18 it, and then Sal incorporated the changes, he sent it</p> <p>19 back to you, and then you signed off on it; is that</p> <p>20 right?</p> <p>21 A. I think that's fair, yes.</p> <p>22 Q. In paragraph 15 of your report, it says</p> <p>23 that within the past four years you've testified as an</p> <p>24 expert at deposition in one other case; do you see</p> <p>25 that?</p>
<p style="text-align: right;">79</p> <p>1 A. We had a couple conversations about what</p> <p>2 would go in the report. He e-mailed a report, it had a</p> <p>3 few blanks, I filled in the blanks and -- you know,</p> <p>4 again, like I said, I don't remember e-mailing or</p> <p>5 whether I picked up the phone or talked to him and had</p> <p>6 completed that part of it and then he sent a final</p> <p>7 draft.</p> <p>8 Q. Okay. You said you had a couple of</p> <p>9 conversations about what would go into the report.</p> <p>10 Do you know how many conversations you had discussing</p> <p>11 what the report would say?</p> <p>12 A. No.</p> <p>13 Q. Do you know how the length -- the total</p> <p>14 length of those conversations about what would go into</p> <p>15 the report?</p> <p>16 A. No. They weren't lengthy.</p> <p>17 Q. An hour?</p> <p>18 A. I don't even think that much.</p> <p>19 Q. Half hour?</p> <p>20 A. Yeah, maybe.</p> <p>21 Q. Then you talked to Sal after you sent him</p> <p>22 the e-mail with your conclusions, you had a couple of</p> <p>23 phone conversations that lasted generally 30 minutes</p> <p>24 and then Sal sent you a draft of the report; is that</p> <p>25 right?</p>	<p style="text-align: right;">81</p> <p>1 A. Yes.</p> <p>2 Q. What case was that?</p> <p>3 A. It was a malpractice case.</p> <p>4 Q. A medical malpractice case?</p> <p>5 A. Yes.</p> <p>6 Q. What role did you serve as an expert in</p> <p>7 that case?</p> <p>8 A. I was giving an opinion for the orthopedic</p> <p>9 surgeon who was being sued in the case.</p> <p>10 Q. The defendant?</p> <p>11 A. Yes.</p> <p>12 Q. Was that Lonnie Paulos?</p> <p>13 A. That was.</p> <p>14 Q. Just generally, can you just describe the</p> <p>15 substance of that opinion? I don't want you to divulge</p> <p>16 any confidentiality, but just --</p> <p>17 A. Well, the substance of the opinion was</p> <p>18 that I didn't feel that he had committed malpractice.</p> <p>19 It was primarily an anesthetic risk case</p> <p>20 and he had been the person operating, so he was</p> <p>21 included in the lawsuit.</p> <p>22 Q. Was Dr. Simon Finger the anesthesiologist?</p> <p>23 A. I'm pretty sure that's correct.</p> <p>24 MR. FALKE: Let's take a break.</p> <p>25 THE VIDEOGRAPHER: Off the record, 5:20.</p>

<p style="text-align: right;">82</p> <p>1 (Brief recess.)</p> <p>2 THE VIDEOGRAPHER: Back on the record on</p> <p>3 record 5:38.</p> <p>4 Q. (By Mr. Falke) Dr. Burks, can you explain</p> <p>5 the knot tie-down analysis that you conducted as</p> <p>6 reflected in Exhibit 232, paragraph 12?</p> <p>7 A. It was taking a strand, tying a knot on</p> <p>8 it, sliding the knot down and then putting another</p> <p>9 knot/half hitch, whatever you want to describe it, and</p> <p>10 sliding it down.</p> <p>11 Q. What did you tie the suture samples on?</p> <p>12 A. A hook.</p> <p>13 Q. What type of hook was it?</p> <p>14 A. Just a simple sort of brass hook.</p> <p>15 Q. Did you use the same knot configuration</p> <p>16 for each comparison?</p> <p>17 A. I used the same knots for the different</p> <p>18 groups, but I varied knots to see how different knots</p> <p>19 might feel.</p> <p>20 Q. But for each knot that you tied on suture</p> <p>21 B, you did that same knot on suture A?</p> <p>22 A. Right, right.</p> <p>23 Q. About how many knots did you tie in total</p> <p>24 in the know tie-down analysis for each suture set,</p> <p>25 generally?</p>	<p style="text-align: right;">84</p> <p>1 A. I mean, I took each strand from each set</p> <p>2 and I tied multiple knots, if you will, in each strand</p> <p>3 so each strand may have had 20 throws in it and. . .</p> <p>4 Q. So does that mean then you did five</p> <p>5 comparisons? You did a knot configuration for each of</p> <p>6 the suture samples?</p> <p>7 MR. TAMBURIO: Objection: mischaracterizes</p> <p>8 the testimony, asked and answered.</p> <p>9 A. I guess I'm trying to go with you, I'm</p> <p>10 just not sure what you. . .</p> <p>11 Q. When you say "comparisons", I mean.</p> <p>12 regardless of the knot configurations or how many</p> <p>13 particular knots were on the one suture, you compared</p> <p>14 that configuration, whatever it is, to the other</p> <p>15 suture set, right?</p> <p>16 A. Correct.</p> <p>17 Q. How many times did you do that?</p> <p>18 MR. TAMBURIO: Objection, vague.</p> <p>19 A. I guess one would say that's five. So the</p> <p>20 five strands in one set got compared to the five</p> <p>21 strands in the other set.</p> <p>22 Q. Right. Did you wet the suture when you did</p> <p>23 the knot tie-down analysis?</p> <p>24 A. Yes.</p> <p>25 Q. How did you wet the sutures?</p>
<p style="text-align: right;">83</p> <p>1 MR. TAMBURIO: Objection, vague.</p> <p>2 A. When you say suture set, you mean the</p> <p>3 group of sutures or the individual strand?</p> <p>4 Q. The set of five.</p> <p>5 A. Okay.</p> <p>6 Q. So as an example, if you did 30 total</p> <p>7 knots is that 15 per suture A and suture B? Let me</p> <p>8 rephrase the question or repeat the question. About</p> <p>9 how many knots did you tie in total for each suture</p> <p>10 set when you did the knot tie-down analysis?</p> <p>11 A. I think it would be, again, hard to give</p> <p>12 you a specific number. I'm not trying to be vague,</p> <p>13 it's just that when you say a knot, for example, I'm</p> <p>14 trying to say that I might throw a half hitch down</p> <p>15 which isn't technically a complete knot, and then I</p> <p>16 might throw another half hitch, so there might be</p> <p>17 multiple half hitches that you could consider one knot</p> <p>18 or you could consider it 20 throws and 20 knots.</p> <p>19 Q. Let me try to help you out there then. How</p> <p>20 many comparisons then did you do in the knot tie-down</p> <p>21 analysis between suture A and suture B?</p> <p>22 MR. TAMBURIO: Objection, vague.</p> <p>23 Q. Do you understand that?</p> <p>24 A. I can tell you what I did and. . .</p> <p>25 Q. Please.</p>	<p style="text-align: right;">85</p> <p>1 A. With tap water.</p> <p>2 Q. Can you explain that?</p> <p>3 A. Sure, I just filled a glass with water and</p> <p>4 put the suture down in it and then tied the knots.</p> <p>5 Q. Did you wet them one at a time?</p> <p>6 A. Yes.</p> <p>7 Q. How long did the suture stay submerged in</p> <p>8 water?</p> <p>9 A. Briefly. Three or four seconds.</p> <p>10 Q. But the same amount of time in the water</p> <p>11 for each suture?</p> <p>12 A. Yes.</p> <p>13 Q. Do you know if the sutures absorb water</p> <p>14 when they're wet?</p> <p>15 A. No.</p> <p>16 Q. You don't know?</p> <p>17 A. No.</p> <p>18 Q. Were each of the -- you come to the</p> <p>19 conclusion in paragraph number 12 of Exhibit 232 that</p> <p>20 when suture A -- there was less friction when sliding</p> <p>21 the knot on the sample labeled suture A as compared</p> <p>22 with sample labeled B. Was that true for all five</p> <p>23 suture samples?</p> <p>24 A. That was a sum feeling on my part. So it</p> <p>25 might not be fair to say it's true on every strand but</p>

22 (Pages 82 to 85)

<p style="text-align: right;">86</p> <p>1 it was my overall take from looking at them.</p> <p>2 Q. Do you remember how many -- strike that.</p> <p>3 Does a suture that has less friction when</p> <p>4 sliding that knot mean that the suture has better knot</p> <p>5 tie-down performance?</p> <p>6 A. Not necessarily.</p> <p>7 Q. Why?</p> <p>8 A. Well, if you envision a perfectly smooth</p> <p>9 suture, for example, if you slide a knot it might</p> <p>10 slide very easily but it might also tend to not hold</p> <p>11 as well because there's not as much inherent friction</p> <p>12 in it.</p> <p>13 Q. Does a smoother suture mean it has better</p> <p>14 tactile feel than a suture that is not as smooth?</p> <p>15 A. I would say no, I don't know that I'd say</p> <p>16 it's a better tactile feel.</p> <p>17 Q. Why did you use a surgeon's knot when you</p> <p>18 did the knot tie-down analysis in Exhibit 232?</p> <p>19 A. I think what I would do is say that --</p> <p>20 again, maybe my critique of the verbiage would be at</p> <p>21 fault. So I guess I wouldn't -- you know, we talked</p> <p>22 earlier about what a surgeon's knot is.</p> <p>23 Q. Uh-huh?</p> <p>24 A. And I probably didn't focus on it enough</p> <p>25 to say that they're not necessarily surgeons' knots as</p>	<p style="text-align: right;">88</p> <p>1 Q. But were there any where you couldn't tell</p> <p>2 a difference? I mean, it was pretty close?</p> <p>3 A. Sure, it was pretty close.</p> <p>4 Q. Let me rephrase. Were there any where you</p> <p>5 couldn't tell the difference between suture A and</p> <p>6 suture B?</p> <p>7 MR. TAMBURO: Objection, asked and</p> <p>8 answered.</p> <p>9 A. I don't remember specifically having ones</p> <p>10 that I would say I clearly feel a difference on this</p> <p>11 one and I clearly don't on the next one. It was a</p> <p>12 general feel of all of them.</p> <p>13 Q. Dr. Burks, how would you describe your</p> <p>14 relationship with Ethicon?</p> <p>15 A. I guess none.</p> <p>16 Q. None? So you would say that you have a</p> <p>17 closer relationship with Arthrex?</p> <p>18 A. Yes.</p> <p>19 Q. What about could you describe your</p> <p>20 relationship with DePuy Mitek?</p> <p>21 A. I have been a consultant with DePuy Mitek.</p> <p>22 Just this week I was helping on an educational course</p> <p>23 for DePuy Mitek reps. But I've had no product or</p> <p>24 anything like that with DePuy Mitek.</p> <p>25 Q. You mean development product work?</p>
<p style="text-align: right;">87</p> <p>1 I described them.</p> <p>2 Q. Okay, so why did you use the particular</p> <p>3 knots, then, that you used in the knot tie-down</p> <p>4 analysis?</p> <p>5 A. I just tried to reproduce what I do in the</p> <p>6 operating room.</p> <p>7 Q. In paragraph 11 in Exhibit 232 you state</p> <p>8 that suture A generally felt smoother than suture B.</p> <p>9 What do you mean by "generally"?</p> <p>10 A. The differences between the sutures were</p> <p>11 subtle. I mean, they were not sharp, distinct. So I'm</p> <p>12 meaning that in comparing them, my take was that it</p> <p>13 was generally smoother.</p> <p>14 Q. Were there any of the sutures in the</p> <p>15 tactile feel analysis where you couldn't tell the</p> <p>16 difference between suture A and suture B?</p> <p>17 A. It was not my intent at the time in</p> <p>18 looking at the sutures to compare each strand side to</p> <p>19 side. My intent was to look at sort of spool A and</p> <p>20 spool B. So it was to get a feel of, in general, how</p> <p>21 do they feel between the two.</p> <p>22 So I didn't take a strand and say is this</p> <p>23 one different? And is this one different? And go</p> <p>24 down through that five times, because I felt it was</p> <p>25 all the same suture.</p>	<p style="text-align: right;">89</p> <p>1 A. Yes.</p> <p>2 Q. What was the educational course this last</p> <p>3 week that you helped with DePuy Mitek?</p> <p>4 A. It was educating reps who go into the</p> <p>5 operating room and, you know, are helping surgeons</p> <p>6 with their materials, sutures, implants, what not, and</p> <p>7 how to handle the operating room environment, be</p> <p>8 appropriate and be helpful.</p> <p>9 Q. The course was not on a particular DePuy</p> <p>10 Mitek technique or anything like that, it was --</p> <p>11 A. It was not focused on a particular product</p> <p>12 but it was focused on helping reps better sell DePuy</p> <p>13 Mitek products.</p> <p>14 Q. By being more professional in the</p> <p>15 operating room?</p> <p>16 A. Correct.</p> <p>17 Q. Is this the first time you have done that</p> <p>18 for DePuy Mitek?</p> <p>19 A. This is the second.</p> <p>20 Q. Other than those two courses, have you</p> <p>21 consulted with DePuy Mitek in any other courses?</p> <p>22 A. Yes.</p> <p>23 Q. What are those?</p> <p>24 A. There was an educational course in Chicago</p> <p>25 and you are going to say when and I'm going to guess</p>

<p style="text-align: right;">90</p> <p>1 four years ago. It was a cadaver course where they 2 were doing DePuy Mitek products and they asked me to 3 come give a couple of talks and help in the lab using 4 those products with the doctors who were there. 5 Q. Do you remember what those products were? 6 A. Not specifically. They were suture 7 anchors, suture passing instruments, but I don't 8 remember a specific product. 9 Q. Are you a consumer of DePuy Mitek 10 products? 11 A. Sure. 12 Q. What DePuy Mitek products do you use? 13 A. Well, I mentioned earlier I use OrthoCord. 14 I use some DePuy Mitek anchors. They make an electric 15 cautery unit that we use. in every case we use 16 electric cautery. 17 They have some suture-passing instruments 18 that we use. I use one of their drill guides and 19 fixation sets for ACL surgery. 20 Q. When you do an ACL fixation, what product 21 do you use? 22 A. It depends on the type of ACL that we're 23 doing. If I use a bone/tendon/bone graft which is a 24 common graft, on the femoral side, I fix it with a 25 DePuy Mitek device which is a couple of absorbable</p>	<p style="text-align: right;">92</p> <p>1 manufacturing state that those sutures have gone 2 through. And I'm wondering if you can look at those. 3 analyze them. do whatever you have to do. but tell me 4 which ones are coated and which ones are not coated. 5 if any? 6 A. So these are three separate types of 7 suture? 8 Q. They're three different sutures. Well. 9 I'm going to take that back. I don't know if they're 10 three different sutures. 11 MR. TAMBURIO: You are not sure what they 12 are. 13 MR. FALKE: We know what they are. yeah. I 14 mean, based on Pearsalls' representations of what they 15 are. If you need to cut them and get you a glass of 16 water, if you want to wet them. 17 MR. TAMBURIO: Are they in the same form in 18 which they were produced? 19 MR. FALKE: Yes, we did not alter them. 20 MR. TAMBURIO: Do we have Bates numbers? 21 Q. Slow down. Just for the record, so the 22 record is clear, what did you just do, Dr. Burks? 23 A. I just opened the suture that was in the 24 bag. 25 Q. What Exhibit Number is that?</p>
<p style="text-align: right;">91</p> <p>1 pins, and on the tibial side I fix it with either a 2 DePuy Mitek screw or a screw from a different company 3 depending on upon quality. 4 On the hamstring, I typically on the 5 femoral side use a Smith and Nephew product -- 6 Q. EndoButton? 7 A. EndoButton. On the tibial side I 8 typically use a Milagro screw and frequently for the 9 post use that Arthrex screw. 10 Q. When you say hamstring, that's soft 11 tissue? 12 A. Correct. 13 Q. Semitendonosis? 14 A. Very good. 15 MR. TAMBURIO: We're all half doctors here. 16 MR. FALKE: Let's take a break. 17 THE VIDEOGRAPHER: Off the record, 5:54. 18 (Brief recess.) 19 THE VIDEOGRAPHER: On the record, 6:02. 20 Q. (By Mr. Falke) Dr. Burks, I'm going to 21 hand you DePuy Mitek Exhibit 286, DePuy Mitek Exhibit 22 284 and DePuy Mitek 285. These are FiberWire samples 23 that were produced to us from Pearsalls who is a 24 company that makes FiberWire for Arthrex. 25 I covered up on those exhibits the</p>	<p style="text-align: right;">93</p> <p>1 A. That is 286. 2 Q. You cut a piece off of the suture in 3 Exhibit 286? 4 A. Right. 5 Q. And -- 6 MR. TAMBURIO: There's no Bates numbers on 7 these? 8 MR. FALKE: There were no Bates numbers. 9 Q. Would you put that on the suture you cut 10 from Exhibit 286 and mark with a pen Exhibit 286. 11 Now, can you explain what you are doing now, Dr. 12 Burks? First, can you put the suture that you took out 13 of 286 back in the bag? 14 A. (Witness complies.) 15 Q. Thank you, and then proceed. Can you 16 explain for the record what you are doing now? 17 A. I'm opening 285. 18 Q. You are cutting suture sample from Exhibit 19 285, right? 20 A. Yes. 21 Q. Could you please mark with the tape 22 Exhibit 285 that you've cut? Proceed. Can you state 23 what for the record what you are doing now? 24 A. I'm opening number 284. 25 Q. And cutting a suture from Exhibit 284?</p>

24 (Pages 90 to 93)

<p style="text-align: right;">94</p> <p>1 A. Yes.</p> <p>2 Q. And now you are going to mark the suture</p> <p>3 sample that you took from Exhibit 284 with a flag?</p> <p>4 A. Correct.</p> <p>5 Q. Can you hand me the original sample sets</p> <p>6 back?</p> <p>7 A. (Witness complies.)</p> <p>8 Q. Also, I'm going to hand you DePuy Mitek</p> <p>9 Exhibit 234 which is a chart I'd like you to fill out</p> <p>10 if you could, please, and under the suture column put</p> <p>11 the numbers corresponding to the suture samples you've</p> <p>12 just cut, just 284, 285 and 286?</p> <p>13 A. Fair enough?</p> <p>14 Q. Fair enough.</p> <p>15 A. Have we got a while?</p> <p>16 Q. However long it takes you.</p> <p>17 MR. TAMBURIO: Are you representing that</p> <p>18 one of them is coated, one of them is not coated?</p> <p>19 MR. FALKE: I'm not making any</p> <p>20 representations. They could all be coated, they could</p> <p>21 all be uncoated, could be a mix?</p> <p>22 A. Can I use your notebook?</p> <p>23 Q. Of course. What do you need?</p> <p>24 A. I was going to use one of those metal</p> <p>25 rings.</p>	<p style="text-align: right;">96</p> <p>1 Q. And 286? Can you explain for the record</p> <p>2 please what you are doing now, Dr. Burks?</p> <p>3 A. I'm tying 284.</p> <p>4 (Discussion off the record.)</p> <p>5 A. Okay. So where is my little sheet here?</p> <p>6 Q. Based on what you've done so far, Dr.</p> <p>7 Burks, can you tell any difference between the</p> <p>8 sutures?</p> <p>9 A. I feel like I do feel a difference.</p> <p>10 Q. Okay. How would you describe that</p> <p>11 difference?</p> <p>12 A. Well, I would say at the moment 285 seems</p> <p>13 a little smoother to me than 284. So I would say 285</p> <p>14 is coated and 284 isn't coated.</p> <p>15 Q. How sure are you of that?</p> <p>16 A. I would not put my children's lives on it,</p> <p>17 but given the subjective feel.</p> <p>18 Q. Is it a subtle difference?</p> <p>19 A. It's a subtle difference.</p> <p>20 Q. Can you explain, Dr. Burks, what you are</p> <p>21 doing now?</p> <p>22 A. Just throwing knots. I would say 286 seems</p> <p>23 coated as well.</p> <p>24 Q. If you had gloves on right now, would that</p> <p>25 change the confidence level you have in determining</p>
<p style="text-align: right;">95</p> <p>1 Q. Sure. First, can you do a tactile feel</p> <p>2 analysis on it? Can you tell the difference?</p> <p>3 A. Kind of -- like I said, when you tie knots</p> <p>4 you combine that together.</p> <p>5 Q. Can you explain what you are doing now?</p> <p>6 A. I don't want to knock your little deal</p> <p>7 off, you know? I'm just getting a sense for how it</p> <p>8 slides and trying to put down a couple of throws.</p> <p>9 Q. Which Exhibit Number are you working on?</p> <p>10 A. I'm on 285.</p> <p>11 Q. Okay. What type of knots are you throwing?</p> <p>12 A. Half hitches.</p> <p>13 Q. Now, can you explain what you are doing,</p> <p>14 Dr. Burks?</p> <p>15 A. Same thing.</p> <p>16 Q. With which exhibit?</p> <p>17 A. 286.</p> <p>18 Q. Are you doing the same thing you did with</p> <p>19 the previous one?</p> <p>20 A. Yes.</p> <p>21 Q. Same knot configurations?</p> <p>22 A. Uh-huh.</p> <p>23 Q. Can you tell a difference between the</p> <p>24 first two sutures, Dr. Burks, Exhibit 285 and --</p> <p>25 A. 286.</p>	<p style="text-align: right;">97</p> <p>1 whether those are coated or uncoated sutures?</p> <p>2 MR. TAMBURIO: Objection, calls for</p> <p>3 speculation.</p> <p>4 A. I think gloves can make a difference,</p> <p>5 yeah.</p> <p>6 Q. How do they make a difference? The</p> <p>7 difference between the sutures is more subtle, right,</p> <p>8 with gloves because you don't have the contact like</p> <p>9 you described earlier with the skin?</p> <p>10 A. Yeah. Again, this is obviously a very</p> <p>11 subjective feel test. Some of that feel comes from how</p> <p>12 the suture feels and some of it comes from how you</p> <p>13 feel when you slide a knot. So we're not talking rocks</p> <p>14 and water as far as differences and so. . .</p> <p>15 Q. How would you qualify the difference that</p> <p>16 you just observed, based on your test?</p> <p>17 A. When you say "qualify" are you asking for</p> <p>18 like an amount?</p> <p>19 Q. How would you characterize the difference</p> <p>20 between the sutures?</p> <p>21 A. Well the difference is, I think, subtle</p> <p>22 and there's no doubt in my mind that I could line up,</p> <p>23 you know, a hundred sutures and have error where I</p> <p>24 would say, you know, I think this one is one way or</p> <p>25 the other and make a mistake.</p>

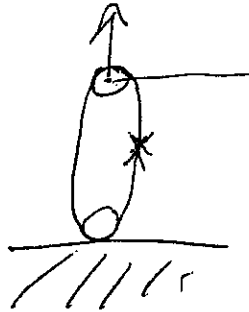
<p style="text-align: right;">98</p> <p>1 So there's certainly not enough difference</p> <p>2 to clearly say that I know every time exactly how that</p> <p>3 feels.</p> <p>4 Q. Okay. Could you just initial, please, the</p> <p>5 chart that you did?</p> <p>6 A. This right here?</p> <p>7 Q. Yes.</p> <p>8 A. Okay.</p> <p>9 Q. And put the date.</p> <p>10 A. (Witness complies.)</p> <p>11 Q. Okay. For the record, I have to mark the</p> <p>12 exhibits, the sutures that you tied onto my binder.</p> <p>13 Can you untie those?</p> <p>14 A. I can just open the binder.</p> <p>15 Q. How confident were you that 286 was</p> <p>16 coated?</p> <p>17 MR. TAMBURO: Objection, vague.</p> <p>18 A. I guess I've said that differences are</p> <p>19 subtle. So I'm going by a subjective feel. So I feel</p> <p>20 like there's a difference. Am I going to bet a lot of</p> <p>21 money on it? No, but that's my take.</p> <p>22 MR. FALKE: Okay. For the record I'm</p> <p>23 going to mark the suture that Dr. Burks tested with</p> <p>24 Exhibit 235 -- I'm going to state that over again.</p> <p>25 For the record, I'm going to mark with</p>	<p style="text-align: right;">100</p> <p>1 Deponent's Certificate</p> <p>2</p> <p>3 I, ROBERT T. BURKS, M.D., deponent herein.</p> <p>4 do hereby certify and declare the within and foregoing</p> <p>5 transcription to be my deposition in said action taken</p> <p>6 on June 7, 2006; that I have read, corrected, and do</p> <p>7 hereby affix my signature to said deposition.</p> <p>8</p> <p>9 DATED this ____ day of _____.</p> <p>10 2006.</p> <p>11</p> <p>12 _____</p> <p>13 Deponent</p> <p>14)</p> <p>14 STATE OF UTAH) ss.</p> <p>15)</p> <p>16 SUBSCRIBED AND SWORN to before me this</p> <p>17 ____ day of _____, 2006.</p> <p>18</p> <p>19 _____</p> <p>20 Notary Public residing in</p> <p>21 _____</p> <p>22</p> <p>23 My Commission Expires:</p> <p>24 _____</p> <p>25</p>
<p style="text-align: right;">99</p> <p>1 Exhibit 235 the suture Exhibit 284 that Dr. Burks just</p> <p>2 tested, and I'm going to mark Dr. Burks' tested suture</p> <p>3 286 with DePuy Mitek Exhibit 236, and I'm going to</p> <p>4 mark Dr. Burks' tested suture 285 with DePuy Mitek</p> <p>5 Exhibit 237.</p> <p>6 I have no further questions.</p> <p>7 EXAMINATION</p> <p>8 BY MR. TAMBURO:</p> <p>9 Q. Dr. Burks, there was some discussion about</p> <p>10 work you had performed on behalf of DePuy Mitek; do</p> <p>11 you recall that?</p> <p>12 A. Yes.</p> <p>13 Q. Were you compensated by DePuy Mitek for</p> <p>14 the work you performed?</p> <p>15 A. Yes.</p> <p>16 MR. TAMBURO: I have no further questions.</p> <p>17 MR. FALKE: Okay, thank you for your time.</p> <p>18 THE VIDEOGRAPHER: End of deposition,</p> <p>19 6:18.</p> <p>20 -O-</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">101</p> <p>1 Reporter's Certificate</p> <p>2 State of Utah)</p> <p>County of Salt Lake)</p> <p>3</p> <p>4 I, Denise Kirk, Certified Shorthand</p> <p>5 Reporter, Registered Professional Reporter, and Notary</p> <p>6 Public for the State of Utah, do hereby certify:</p> <p>7 THAT the foregoing proceedings were taken</p> <p>8 before me at the time and place set forth herein; that</p> <p>9 the witness was duly sworn to tell the truth, the</p> <p>10 whole truth, and nothing but the truth; and that the</p> <p>11 proceedings were taken down by me in shorthand and</p> <p>12 thereafter transcribed into typewriting under my</p> <p>13 direction and supervision;</p> <p>14 THAT the foregoing pages contain a true</p> <p>15 and correct transcription of my said shorthand notes</p> <p>16 so taken.</p> <p>17 IN WITNESS WHEREOF, I have subscribed my</p> <p>18 name and affixed my seal this 11th day of June, 2006.</p> <p>19</p> <p>20 _____</p> <p>21 DENISE KIRK, CSR/RPR</p> <p>22 My commission expires:</p> <p>23 August 30, 2006</p> <p>24</p> <p>25</p>

BROOKSTEIN DECLARATION EXHIBIT 24

DEPUY MITEK
EXHIBIT 113
04cv12457

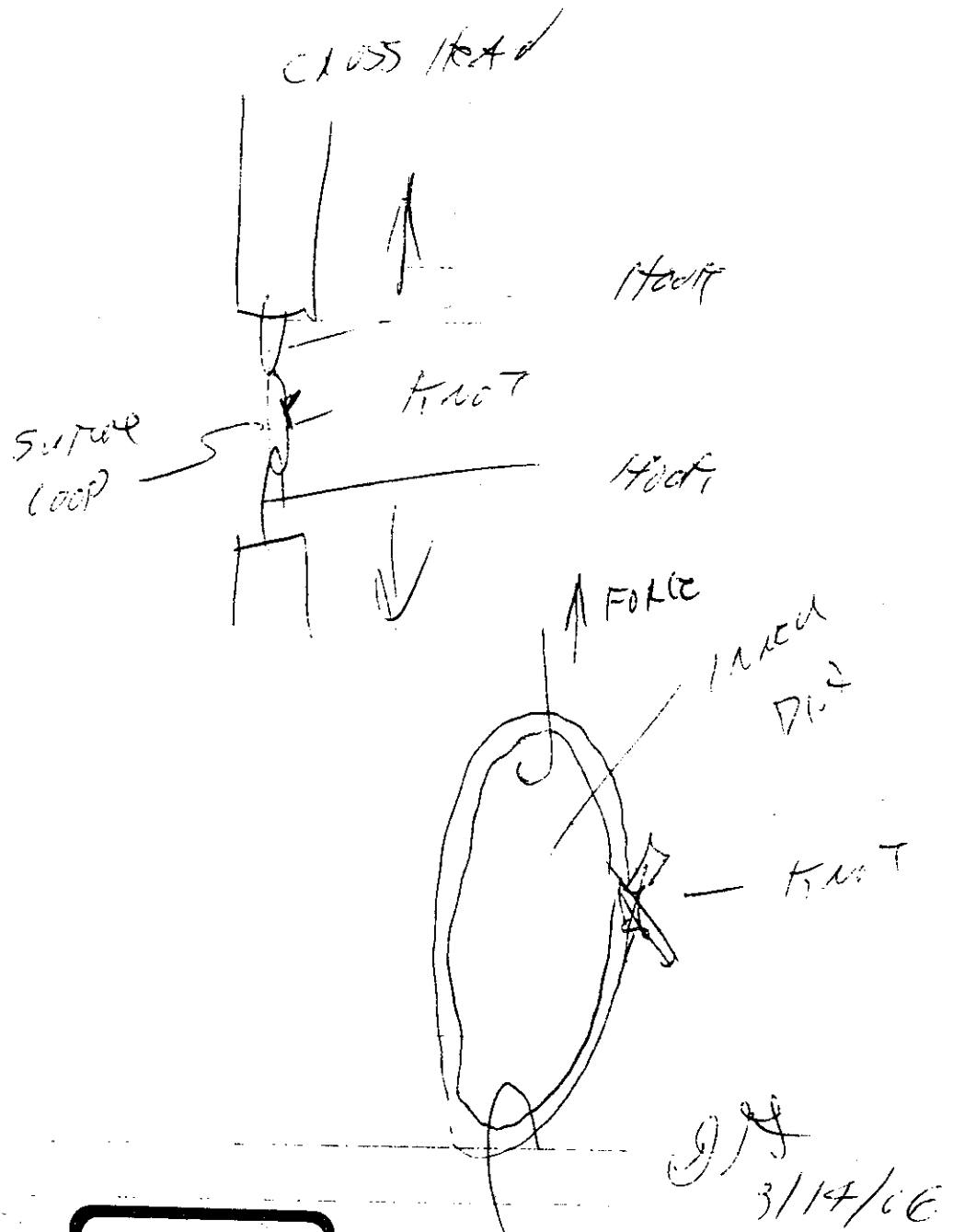
Knot Security

~~Side~~
Front View



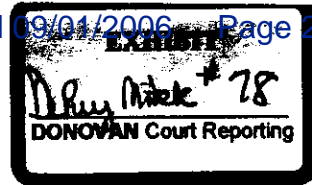
A. H. 09/15/05

BROOKSTEIN DECLARATION EXHIBIT 25



DEPUY MITEK
EXHIBIT 421
04cv12457

BROOKSTEIN DECLARATION EXHIBIT 26



78

February 28, 2001

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation 510(k)
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Re: 510(k) Premarket Notification: Arthrex FiberWIRE™

Dear Ladies and Gentlemen:

This is to notify you of the intention of Arthrex, Inc. to market the above referenced medical device in the United States. We are seeking permission to market the device for the following intended use: general soft tissue approximation, and/or ligation.

This submission is submitted in duplicate and is provided to comply with Section 510(k) Premarket Notification of the Federal Food, Drug and Cosmetic Act in conformance with CFR Title 21, Part 807 Subpart E. This submission includes provisions related to 510(k)'s in the Safe Medical Devices Act of 1990 (SMDA), Public Law 101-629.


Arthrex, Inc. regards the referenced Arthrex FiberWIRE™ to be 'substantially equivalent' as defined for use under the Act to devices of the same type that were in commercial distribution prior to May 28, 1976, or equivalent. The enclosed information addresses the requirements of the Act pertaining to this 510(k) Notification.

We request that the Food and Drug Administration hold as commercial confidential information the intent to market this device for this indication to the fullest extent as authorized by law.

Specific information is submitted as listed in the TABLE OF CONTENTS, Appendix 1 through Appendix 8.

Thank you for your assistance in this matter.

Sincerely,


L. Brette Masino
Regulatory Affairs

CONFIDENTIAL - NON-PATENT
PROSECUTION COUNSEL
ONLY

ARM 001888

**Arthrex FiberWIRE™ Braided Polyblend Suture
Non Absorbable Surgical Suture, USP & EP Conformance**

Description

Arthrex FiberWIRE™ is a blend of long chain polyesters braided and sterilized for surgical use. Arthrex FiberWIRE™ is coated with a silica reinforced polydimethylsiloxane. The coating acts as a lubricant for suture sliding and knot tying and ease of passing the suture through tissue.

Arthrex FiberWIRE™ is available in non-dyed (white) or dyed (D & C Blue No. 6) and exceeds USP and EP standards for diameter, knot strength and straight pull strength.

Indications

Arthrex FiberWIRE™ is indicated for use in soft tissue approximation and or ligation.

Actions

Arthrex FiberWIRE™ elicits minimal acute inflammatory reaction in tissue, as evidenced by in vivo testing. Polyester suture has been shown to become encapsulated by fibrous connective tissue during healing. The polyester suture, Dye (D&C Blue No. 6), and diperoxide silicone oil (coating) are pharmacologically inactive.

Contraindications

None Known

Warnings

Users should be familiar with surgical procedures and techniques for using non-absorbable suture including wound closure and knot tying.

Do not resterilize. Do not use suture from previously opened or damaged packages.

Precautions

Care should be taken when handling braided suture to prevent damage to the individual filaments from abrasion or crimping which could effect the mechanical characteristics of the suture. Do not expose to heat. Assure all knots have been secured using accepted surgical knot tying techniques. Care should be taken to prevent damage to surrounding tissue or user puncture due to improper handling of the needlepoint.

CONFIDENTIAL - NON-PATENT
PROSECUTION COUNSEL
ONLY

000032

ARM 001976

EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION

NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

DEPOSITION OF: DONALD GRAFTON
DATE: March 14, 2006
TIME: 8:38 a.m. to 1:23 p.m.
LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112
TAKEN BY: Plaintiff
REPORTER: Deborah A. Krotz, RPR, CRR
VIDEOGRAPHER: Gene Howell, CLVS

<p>18</p> <p>1 Q. And who located -- Did you locate them?</p> <p>2 A. I believe so.</p> <p>3 Q. And how did you come about locating Pearsalls?</p> <p>4 A. I don't remember.</p> <p>5 Q. Did you have a contact there or --</p> <p>6 A. There is a contact, yes.</p> <p>7 Q. Did you have a contact person or --</p> <p>8 A. I can't tell you how I found Pearsalls right now.</p> <p>9 Q. When Arthrex began selling sutures from</p> <p>10 Pearsalls, what size --</p> <p>11 A. Size 2.</p> <p>12 Q. Size 2. Any others?</p> <p>13 A. Possibly Size 1, but I'm not sure.</p> <p>14 Q. Okay. FiberWire started being sold in about</p> <p>15 August 2001; is that right?</p> <p>16 A. Okay. I don't know.</p> <p>17 Q. Does that sound right?</p> <p>18 A. I -- Hey, I'm not a calendar. I can't tell you</p> <p>19 that. There -- We've got sales records that you can look</p> <p>20 up, and you can find out exactly when it was sold. That</p> <p>21 would be much better than asking me to chronologically</p> <p>22 give you a calendar date.</p> <p>23 Q. I'm just looking for a rough time.</p> <p>24 A. Look at -- find sales invoices and see when it</p> <p>25 was sold, sir.</p>	<p>20</p> <p>1 A. I have no idea.</p> <p>2 Q. How about strength? Any problems with the</p> <p>3 strength of the 100 percent polyester suture?</p> <p>4 A. Not that I recall.</p> <p>5 Q. You said -- I think you also said it was -- when</p> <p>6 I first asked you if they had any problems with the 100</p> <p>7 percent polyester suture from Pearsalls, I think you, in</p> <p>8 addition to saying it was not as compliant, you also said</p> <p>9 it was stiff. What did you mean by stiff?</p> <p>10 A. Not as compliant.</p> <p>11 Q. Same thing?</p> <p>12 A. (Witness nods head affirmatively).</p> <p>13 Q. You didn't mean anything different in your mind?</p> <p>14 A. No.</p> <p>15 Q. Any knot strength problems with the 100 percent</p> <p>16 polyester suture from Pearsalls?</p> <p>17 A. From Pearsalls? Not that I recall.</p> <p>18 Q. Okay. What was the next suture after -- Well,</p> <p>19 let me back up. Were you involved at all with Mr. Hallett</p> <p>20 or Mr. Lawson when selecting this 100 percent polyester</p> <p>21 suture from Pearsalls?</p> <p>22 A. Yes.</p> <p>23 Q. Were they your main contacts there?</p> <p>24 A. Correct.</p> <p>25 Q. Was this a suture that Pearsalls had designed for</p>
<p>19</p> <p>1 Q. I'm just trying to find out what you remember.</p> <p>2 A. Very little.</p> <p>3 Q. Okay. Any problems with this polyester suture</p> <p>4 from Arthrex? I'm sorry. I'm sorry.</p> <p>5 MR. SOFFEN: Objection.</p> <p>6 Q. Let me rephrase the question. Was there any</p> <p>7 problem with this polyester suture from Pearsalls?</p> <p>8 A. It was stiff. And the -- that was the main</p> <p>9 complaint; although when I say complaint, it was not a</p> <p>10 widely-spread complaint. But the suture was not as</p> <p>11 compliant as the sutures that were on competitive anchors.</p> <p>12 Q. And some of the sutures that were on competitive</p> <p>13 anchors were Ethibond?</p> <p>14 A. That's correct.</p> <p>15 Q. So this 100 percent polyester suture from</p> <p>16 Pearsalls was not as compliant as Ethibond?</p> <p>17 A. Yes.</p> <p>18 Q. When you say not as compliant, what do you mean</p> <p>19 by that?</p> <p>20 A. Surgical feel, tactile feel of the suture by the</p> <p>21 surgeon.</p> <p>22 Q. Did the 100 percent polyester suture from</p> <p>23 Pearsalls have a coating on it?</p> <p>24 A. Yes.</p> <p>25 Q. What was the coating?</p>	<p>21</p> <p>1 Arthrex, this 100 percent polyester suture, or is this one</p> <p>2 that was already being made?</p> <p>3 A. I don't remember.</p> <p>4 Q. You don't remember?</p> <p>5 Sorry; I misspoke earlier. I said Mr. Lawson.</p> <p>6 And I should have said Mr. Lyon. It's Lawson Lyon.</p> <p>7 A. Yes.</p> <p>8 Q. Sorry. Let me just reask the question so the</p> <p>9 record is clear. When you were -- had selected the 100</p> <p>10 percent polyester suture from Pearsalls, you were involved</p> <p>11 with Mr. Hallett and Mr. Lyon from Pearsalls?</p> <p>12 A. Yes. And when you say 100 percent, are you</p> <p>13 talking about only the substrate material, or are you</p> <p>14 talking about additives such as dye or coating? Because</p> <p>15 those -- those would be on the suture. So when you say</p> <p>16 100 percent, that's not totally accurate.</p> <p>17 Q. Okay. Was suture -- Let's just call it polyester</p> <p>18 suture.</p> <p>19 A. Okay.</p> <p>20 Q. The polyester suture, do you recall, from</p> <p>21 Pearsalls, did it have a coating on it?</p> <p>22 MR. SOFFEN: Objection; asked and answered.</p> <p>23 A. Yes. Yes.</p> <p>24 Q. Okay. But you don't recall the type of coating?</p> <p>25 A. No.</p>

6 (Pages 18 to 21)

<p style="text-align: right;">50</p> <p>1 ultra-high molecular weight polyethylene or if it was 2 braided or -- 3 A. It's been too long ago. I can't tell you that. 4 Q. And your idea was to use the ultra-high molecular 5 weight polyethylene as a suture? 6 A. Yes. 7 Q. Okay. And you had Mr. Hallett make a Size 2, I 8 think you said? 9 A. Yes. 10 Q. Okay. Can you describe the construction of that 11 first -- 12 A. I don't remember now. It's been too long. 13 Q. Was it all ultra -- ultra-high molecular weight 14 polyethylene? 15 A. Initially, yes, as a test prototype material. 16 Q. Was it braided? 17 A. Yes. 18 Q. Was it an eight-carrier or a sixteen-carrier? 19 A. I don't remember. 20 Q. You said it was a Size 2 though? 21 A. Yes. 22 Q. So it was a Size 2 ultra-high molecular weight 23 polyethylene braided suture that did not have PET? 24 A. For the initial prototype material, that's 25 correct.</p>	<p style="text-align: right;">52</p> <p>1 Q. Knot security test? 2 A. Yes. 3 Q. Was that the test we drew in Exhibit Number 421? 4 A. That's correct. 5 Q. Okay. And you said the strength was excellent, I 6 believe, of the initial prototype, but the knot slippage 7 was poor; is that right? 8 A. Yes. 9 Q. Okay. When you say the slippage was poor of the 10 initial prototype, what do you mean? 11 A. Less than the tensile strength capability of the 12 existing Arthrex product. 13 Q. So the knot slippage was less than the Tevdek 14 suture? 15 A. Yes. 16 Q. And it was -- knot slippage was such that it was 17 determined that the 100 percent ultra-high molecular 18 weight polyethylene suture prototype wasn't suitable to be 19 developed? 20 A. That's correct. Yes. 21 Q. Okay. Ultra-high molecular weight polyethylene, 22 you said the knot slippage was poor? 23 A. (Witness nods head affirmatively). 24 Q. Ultra-high molecular weight polyethylene, is that 25 a lubricious material?</p>
<p style="text-align: right;">51</p> <p>1 Q. Okay. And it didn't have nylon or any other 2 material braided with it? 3 A. No. 4 Q. So the initial prototype was a ultra-high 5 molecular weight polyethylene braided suture prototype, if 6 you will? 7 A. Yes. Size 2. 8 Q. Size 2. And was the initial prototype, was it 9 coated? 10 A. I don't remember. 11 Q. Okay. Do you know if the initial prototype went 12 through any other manufacturing process like stretching or 13 heating, twisting? 14 A. I don't recall. 15 Q. Was the initial prototype 100 percent ultra-high 16 molecular weight polyethylene? 17 A. For the fourth time, yes. 18 Q. Okay. And you tested the initial prototype that 19 was 100 percent ultra-high molecular weight polyethylene 20 with Dr. Burkhardt and Dr. Chen? 21 A. Dr. Casey Chen, correct. 22 Q. Okay. And the test that you conducted with Dr. 23 Burkhardt and Dr. Chen on the ultra-high molecular weight 24 polyethylene was a knot strength test? 25 A. Knot security.</p>	<p style="text-align: right;">53</p> <p>1 A. Yes. 2 Q. And was the knot slippage of this ultra-high 3 molecular weight polyethylene poor security because of the 4 lubricity of polyethylene? 5 A. Yes. 6 Q. Yes? 7 A. Yes. 8 Q. So then you came up with the idea to braid PET 9 with the ultra-high molecular weight polyethylene to 10 reduce the knot slippage? 11 A. Yes. 12 Q. And when you say knot slippage, we're referring 13 to this knot security test? 14 A. Yes. 15 Q. So are we using the terms knot slippage and knot 16 security interchangeably here? 17 A. You are, yes. 18 Q. In your testimony? 19 A. Yes. 20 Q. So the knot security of the 100 percent 21 ultra-high molecular weight polyethylene was poor, the 22 prototype; right? 23 A. Yes. 24 Q. And your idea was to add the PET and to improve 25 the knot security?</p>

14 (Pages 50 to 53)

<p style="text-align: right;">54</p> <p>1 MR. SOFFEN: Objection; asked and answered. 2 You've asked him the same thing multiple times. But 3 you can answer. 4 A. I've lost count, it's been so many times, but the 5 answer again is yes. 6 Q. Okay. And Dr. Burkhart said that was a killer 7 idea? 8 A. What was a killer idea? 9 Q. The killer idea was that your idea of adding 10 PED -- PET -- I'm sorry. I'll rephrase that question. 11 Did Dr. Burkhart say that your idea to braid PET 12 with the ultra-high molecular weight polyethylene to 13 improve knot security was a killer idea? 14 A. Yes. 15 Q. Okay. And then you said you had Pearsalls 16 manufacture a prototype that had PET and ultra-high 17 molecular weight polyethylene braided? 18 A. Yes. 19 Q. And you tested that prototype? 20 A. Yes. 21 Q. And you said that that prototype had good knot 22 strength? 23 A. Correct. 24 Q. And the prototype of PET braided with ultra-high 25 molecular weight polyethylene had good knot security?</p>	<p style="text-align: right;">56</p> <p>1 Q. I'm talking about the -- 2 A. The second prototype with the PET? 3 Q. Correct. 4 A. Yes. 5 Q. The second prototype that had the coating on it? 6 A. Yes. 7 Q. And was that part of your initial idea, or was 8 that -- because I thought you said your initial idea was 9 to add the PET. Was it also to coat it, or was that 10 something that came later? 11 A. If you're going to market the product, it needs 12 the coating on it, sir. 13 Q. Okay. But the prototype that was manufactured 14 that you asked -- 15 A. Most likely, it was coated, because it needed to 16 be as the final product would be marketed. 17 Q. You said most likely. Do you remember or you 18 don't remember whether the prototype that had the PET and 19 the ultra-high molecular weight polyethylene was coated? 20 A. I can't tell you for sure that it was at that 21 prototype stage. 22 Q. Okay. Was this prototype that you had -- after 23 you tested the prototype with PET with ultra-high -- 24 A. Excuse me. I want to change that. 25 Q. Okay.</p>
<p style="text-align: right;">55</p> <p>1 A. Yes. 2 Q. And the prototype of PET and ultra-high molecular 3 weight polyethylene braided together also had good tensile 4 strength? 5 A. Yes. 6 Q. And after you tested this second prototype, if 7 you will, of the PET braided with ultra-high molecular 8 weight polyethylene, was then the decision made to pursue 9 trying to commercially develop this idea? 10 A. Yes. 11 Q. Did you -- when you made -- Who made the decision 12 to go forward and try to commercialize this idea? 13 A. Myself and Reinhold, surgeons that we 14 collaborated with, marketing people. You know, it wasn't 15 just myself. 16 Q. Okay. Was this prototype that had the PET 17 braided with the ultra-high molecular weight polyethylene, 18 was it -- did it have a coating on it? 19 A. Yes. 20 Q. It did? 21 A. (Witness nods head affirmatively). 22 Q. And what was the coating? 23 A. I forget the name. It's like an MED2174s. 24 Q. That was on the prototype? 25 A. Which prototype are you referring to now?</p>	<p style="text-align: right;">57</p> <p>1 A. I never got samples of constructions from 2 Pearsalls without a coating unless I specifically asked 3 for it not to be coated. So there's a very high 4 probability that the suture came as -- the second 5 prototype -- as coated. 6 Q. That was standard for them to coat it, in other 7 words? 8 A. Yes. 9 Q. Okay. So the initial prototype that was 10 ultra-high molecular weight polyethylene, did you ask for 11 that not to be coated? 12 A. No. 13 Q. So chances are that that one was coated? 14 A. Quite possibly. 15 Q. After you tested the prototype of PET and 16 ultra-high molecular weight polyethylene braided together, 17 did you believe that it would then work as a suture? 18 A. Yes. 19 Q. Okay. Is there anything else you think you 20 needed to do in order to determine whether it would work 21 as a suture? 22 A. Yes. 23 Q. What did you need to do? 24 A. Biocompatibility toxicity testing, bioburden 25 levels, all the design control GNP items that need to be</p>

EXHIBIT 18

Deposition of:
Dr. Mark G. Steckel

January 26, 2006

Page 1

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4

**TRAVEL
TRANSCRIPT**

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
10 Defendants.)
11

12 DEPOSITION of DR. MARK G. STECKEL,
13 called as a witness by and on behalf of the
14 Defendant, pursuant to the applicable provisions of
15 the Federal Rules of Civil Procedure, before P.
16 Jodi Ohnemus, Notary Public, Certified Shorthand
17 Reporter, Certified Realtime Reporter, and
18 Registered Merit Reporter, within and for the
19 Commonwealth of Massachusetts, at the Courtyard
20 Marriott, 423 Speen Street, Natick, Massachusetts,
21 on Thursday, 26 January, 2006, commencing at 10:44
22 a.m.
23
24
25

Page 106

1 A. We were certainly looking at fiber. We
2 were certainly considering fibers that offer higher
3 tensile strength than -- than strictly PET.
4 **Q. And that was the aromids?**
5 MR. BONELLA: Object to form.
6 A. That was one of -- that was one example.
7 **Q. Is there anything else?**
8 MR. BONELLA: In the patent?
9 MR. SABER: Yes, sir.
10 MR. BONELLA: If you want to read the
11 patent, read the patent. Object to form.
12 A. Well, the patent describes generic classes
13 of polymers, and the high strength aspect of it has
14 more to do with how those polymers were processed.
15 So, any of those polymers that are listed, you
16 know, could be processed in a high strength form or
17 a medium-strength form or a low-strength form.
18 **Q. When you're saying, "these," which ones**
19 **are you talking about?**
20 A. I'm referring to the polymers listed in
21 the claims.
22 **Q. All of them?**
23 A. All of those can be processed to get a
24 range of low, medium, or relatively high strength.
25 **Q. All right. Let's look at the**

Page 107

1 **specification, if we could.**
2 A. Okay.
3 **Q. Could you look at Column 4, please. Yes.**
4 **The paragraph that starts at Line 33.**
5 A. Yes.
6 **Q. Is that paragraph disclosing the polymers**
7 **which are to act as strength --**
8 MR. BONELLA: Object --
9 **Q. -- to provide improved strength to the**
10 **braid?**
11 MR. BONELLA: Object to form.
12 A. (Witness reviews document.) I'm sorry.
13 Could you repeat the question.
14 **Q. Yeah.**
15 MR. SABER: Could you read it back,
16 please.
17 (Question read back.)
18 MR. BONELLA: Object to form.
19 **Q. Let me rephrase that. Does that paragraph**
20 **provide suggested polymers to provide improved**
21 **strength to the braid?**
22 MR. BONELLA: Object to form.
23 A. That paragraph describes two sets of --
24 that describes "Lubricating yarns in the first
25 set --"

Page 108

1 **Q. Right, in the first set.**
2 A. Right.
3 **Q. "-- that are mechanically blended with**
4 **yarns of the second set, which act to provide**
5 **improved strength to the heterogeneous braid."**
6 **Isn't that talking about the second set, providing**
7 **"improved strength to the heterogeneous braid"?**
8 A. Yeah, within the context of this
9 paragraph. But once again, PET, for example, could
10 be, you know, could be in a -- in a low strength or
11 medium strength or a high strength.
12 **Q. I'm talking about what's being -- what's**
13 **being explained in this paragraph.**
14 A. Okay.
15 **Q. Is this -- isn't it true that this**
16 **paragraph is explaining that the -- that the yarns**
17 **from the second set are there to provide improved**
18 **strength to the braid?**
19 MR. BONELLA: Object to form.
20 A. My read of this is that in this particular
21 embodiment, the second set would be offering
22 strength.
23 **Q. And that's the only yarns that are**
24 **specifically mentioned are PET, nylon, and aromids,**
25 **is that correct?**

Page 109

1 MR. BONELLA: Object to form.
2 A. Those --
3 **Q. As providing the strength.**
4 A. Those are the only --
5 MR. BONELLA: Object to form.
6 A. -- ones mentioned.
7 **Q. In that paragraph?**
8 A. As far -- yes.
9 **Q. Is there any other mention in this patent**
10 **-- specific mention of any other yarn there to**
11 **provide strength?**
12 MR. BONELLA: In the patent?
13 MR. SABER: Yes, sir.
14 MR. BONELLA: If he needs to read the
15 patent, read the entire patent to answer the
16 question then.
17 A. Are there any other fibers mentioned --
18 **Q. Any other yarns mentioned to provide**
19 **strength --**
20 A. I would say.
21 **Q. -- to the --**
22 A. Any of the polymers that we mentioned
23 could be the strength.
24 **Q. Could you tell me where it says that. I**
25 **want to know exactly what you're relying upon in**

28 (Pages 106 to 109)